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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

HOLOGIC, INC., CYTYC CORPORATION, and HOLOGIC LP, Plaintiffs, vs. SENORX, INC., Defendant.	Case No. C08-00133-MEJ **PLAINTIFFS' NOTICE OF MOTION AND MOTION FOR PRELIMINARY INJUNCTION** **Date: March 20, 2008** **Time: 10:00a.m.** **Courtroom: B, 15th floor** **Judge: Hon. Maria-Elena James**

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Please take notice that on March 20, 2008 at 10:00 a.m., or as soon thereafter as counsel may be heard, in the courtroom of the Honorable James, at: SF Courtroom B, 15th floor, 450 Golden Gate Avenue, San Francisco, CA 94102 Plaintiffs Hologic, Inc., Cytyc Corporation, and Hologic, LP (together, "Hologic"), by counsel and pursuant to 35 U.S.C. § 283 and Rule 65 of the Federal Rules of Civil Procedure, will move this Court to preliminarily enjoin SenoRx, Inc. ("SenoRx") from infringement of Claim 36 of U.S. Patent No. 6,413,204 (the "'204 patent") and claim 1 of U.S Patent No. 6,482,142 (the "'142 patent"), specifically by enjoining SenoRx from selling and/or offering to sell the Contura™ Multi-Lumen Balloon ("Contura MLB"). A Proposed Order is attached.

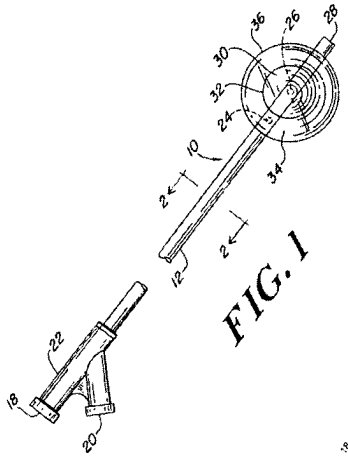
This Motion is based on the following Memorandum of Points and Authorities, the declarations of Glenn Magnuson and Katharine L. Altemus filed in support, all other pleadings and relevant evidence of record, and the arguments of Hologic's counsel.

MEMORANDUM OF POINTS AND AUTHORITIES

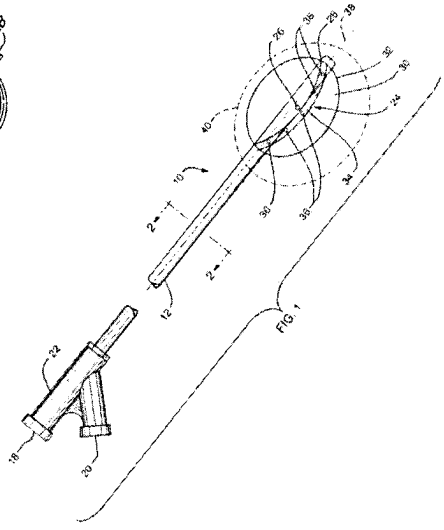
I. INTRODUCTION

The products at issue are catheter systems used to deliver life-saving radionuclide-based radiation therapy, typically to post-lumpectomy breast cancer patients. Below left is a depiction of the accused product from recent marketing materials; on the right are figures from the patents in suit:

Contura MLB



'204 Patent FIG. 1



'142 Patent FIG. 1

In December 2007, SenoRx announced in a press release that it would begin commercialization of the infringing Contura MLB in January 2008. Hologic filed this suit immediately thereafter. On January 17, 2008, SenoRx announced that a full commercial launch of the Contura MLB had begun. By this Motion, Hologic seeks to stop this imminent wide-scale infringement of its patents and attendant irreparable injury that will result from SenoRx's market entry.

All of the preliminary injunction factors favor Hologic. *First*, Hologic is likely to win on the merits at trial – indeed, Hologic expects, well before trial – as the Contura MLB plainly infringes the Patents-In-Suit. That outcome is all the more likely in light of the fact that, in a previous litigation, this Court has already construed many of the claim terms that will be at issue here in a manner that squarely implicates the Contura MLB and, as part of that construction process, rejected a number of invalidity assertions under 35 U.S.C. 112. *Second*, Hologic will be irreparably harmed by SenoRx's unlawful entry into the market for a number of reasons. Most significant is SenoRx's apparent pricing strategy, *i.e.*, an effort to gain share through discounting, which will forever change the market and prevent Hologic from recouping its investment in the patented technology. Also of great concern is SenoRx's likely inability ever to pay a damages verdict. SenoRx also appears to be promoting its device in a manner inconsistent with the device labeling without any clinical data to support that promotion – such harmful practices could harm the reputation of brachytherapy as a treatment modality. Further possible forms of irreparable harm are also manifest, as will be discussed. *Third*, the balance of harms clearly weighs in Hologic's favor. SenoRx's business is diagnostics products, not treatment products like the Contura MLB. An injunction barring infringing sales would leave it no worse off than it is today. Hologic, on the other hand, would suffer substantial loss of revenue and goodwill that could never be recovered after SenoRx permanently alters the market, *e.g.*, through price erosion and damaged reputation to Hologic and/or to the brachytherapy treatment modality. *Finally,* a preliminary injunction would serve the public interest by protecting a patent holder's rights to recoup its substantial R&D investment through exclusivity in the market that it created.

II. STATEMENT OF THE ISSUE TO BE DECIDED

This Motion presents the following issue for decision by this Court: Should SenoRx be preliminarily enjoined from infringement of claim 36 of the '204 patent and claim 1 of the '142 patent (the "Preliminary Asserted Claims")?

III. STATEMENT OF RELEVANT FACTS

A. Hologic Is A Pioneer In Breast Brachytherapy

1. Hologic's MammoSite Revolutionized Breast Radiation Therapy

Following the surgical removal of a cancerous tumor from a breast, known as "resection," radiation therapy is usually required to ensure that all the cancerous cells in the vicinity of the tumor are killed. Declaration of Glenn Magnuson In Support Of Plaintiffs' Motion For Preliminary Injunction ("Magnuson Decl."), ¶ 4. One such treatment option for patients undergoing breast conservation therapy is partial breast irradiation, where only a targeted portion of the breast tissue is irradiated. *Id.* Today, the most widely practiced method of partial breast irradiation is breast brachytherapy utilizing Hologic's MammoSite® Radiation Therapy System ("MammoSite").[1] *Id.* Indeed, Proxima, then Cytyc and Hologic created a new breast brachytherapy market using this technology. *Id.*

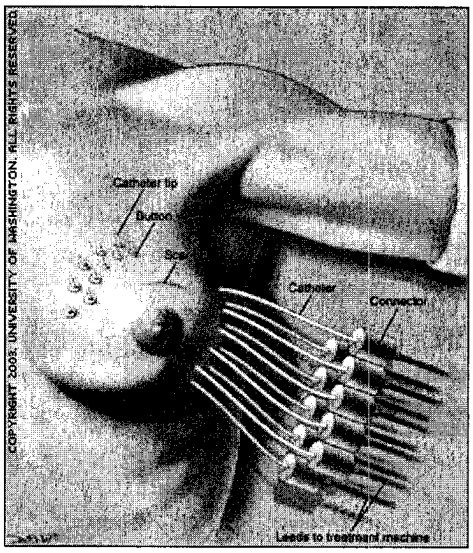
The MammoSite is employed to treat the breast using a radiation source that is placed inside the surgical cavity – called "interstitial brachytherapy." *Id.*, ¶ 5. This has four key advantages:

- Radiation is delivered inside the breast tissue directly to the area where cancer is most likely to recur.
- This targeting of the cancerous tissue bed minimizes radiation exposure to healthy tissue, thereby minimizing the potential for side effects.
- The therapy can be completed in just a few days.
- Radiation therapy can be completed before beginning chemotherapy (if prescribed).

[1] "Brachytherapy" refers to "radiation therapy delivered by a spatially-confined radioactive material inserted into the body at or near a tumor or other proliferative tissue disease site." Ex. L to the Declaration of Katharine L. Altemus in support of Plaintiffs' Motion for Preliminary Injunction ("Altemus Decl.").

Id. Because breast brachytherapy using the MammoSite can shorten the treatment period, the technique is sometimes generically referred to as accelerated partial breast irradiation ("APBI"). It can be contrasted with external beam radiation therapy, which can require a course of six to eight weeks and can expose healthy tissue to unwanted radiation. *Id.*

For many years, interstitial brachytherapy was provided to breast cancer patients by implanting multiple (up to 30) catheters in the breast. Magnuson Decl. ¶ 6. After placement of the catheters, a radioactive seed was delivered into each catheter to treat the target area. *Id.* The seed was delivered into each catheter twice a day, typically for 5 days. *Id.* The total treatment time for each session was approximately 20 minutes. When treatment was complete, the catheters were removed from the breast. *Id.* Given the number of catheters inserted into the breast, these procedures were often painful and left unpleasant scars. *Id.* As a result, many cancer patients would elect no post surgical treatment, thereby significantly increasing the risk of recurrence. *Id.* The figure below, from the website of the University of Washington Medical Center, illustrates conventional interstitial brachytherapy (with 10 catheters):

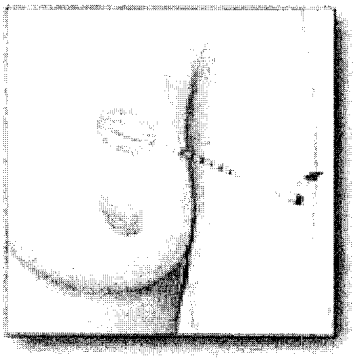


Conventional interstitial brachytherapy with 10 catheters

Magnuson Decl., ¶ 7.

A startup company called Proxima Therapeutics, Inc. ("Proxima") revolutionized interstitial breast brachytherapy with its development of a novel balloon catheter system, later commercialized as MammoSite, for delivering the radiation source directly to the target breast tissue. The novel catheter

system required the insertion of a single balloon applicator into the surgical site, as shown in the below image from *www.mammosite.com*:



MammoSite interstitial brachytherapy with a single catheter

Magnuson Decl., ¶ 8. Proxima obtained patent protection on its system, including the three Patents-In-Suit. Cytyc acquired Proxima and its patented balloon brachytherapy system in March 2005, and Hologic joined with Cytyc in October 2007. *Id.*

Hologic's MammoSite is currently the most widely used method of partial breast irradiation. Magnuson Decl., ¶ 9. MammoSite places the radiation source (contained within a balloon applicator) inside the lumpectomy cavity (the space left when a tumor is removed), and delivers a high dose of radiation to the area most at risk for recurrence while limiting the radiation dose to the surrounding normal breast and adjacent tissues. *Id.* Therapy with MammoSite is given on an outpatient basis, and no hospital stay is required. Cosmetic outcome is good to excellent, and patient satisfaction has been overwhelmingly positive. *Id.* As a result, more women are electing post surgical treatment, which is believed to have an overall positive impact by reducing the post-surgical recurrence rate.

The creation and development of the APBI market took significant investment by Proxima, Cytyc, and Hologic. Magnuson Decl., ¶ 10. Before Proxima marketed the MammoSite, it conducted animal studies and clinical trials to characterize the therapeutic effects and potential side effects of treatment with MammoSite. *Id.* To further develop the APBI market, Proxima, Cytyc, and then Hologic have expended considerable effort and expense to educate breast surgeons and radiation oncologists about the MammoSite product, to analyze the clinical data that have been accumulating over the last five years of patient use, and to make further improvements to the MammoSite product. *Id.* These efforts have included sponsoring symposia and the publication of papers on MammoSite use, training physicians to use the MammoSite technology appropriately and effectively, working with

the American Society of Breast Surgeons to institute a patient registry to monitor possible health problems associated with the use of MammoSite, and engaging in continuing product research and development. *Id.* In addition, Proxima, then Cytyc and Hologic, had to lobby for the provision of reimbursement codes so that the MammoSite procedure could be covered by patents' insurance policies. *Id.* As a result of these efforts, Hologic has gained the trust and good will of the health care community. *Id.* All told, Hologic and its predecessors invested Redacted in the research, development, and marketing of the MammoSite and the APBI market. *Id.*

2. Hologic Protected Its Investment By Obtaining The Patents-In-Suit

The MammoSite practices technology disclosed in the Patents-In-Suit, which are directed specifically to a type of brachytherapy known as "interstitial" brachytherapy, in which, as this Court found, radiation therapy is delivered by a spatially-confined radioactive material inserted into a surgically-created cavity in a body at or near a tumor or other proliferative tissue disease site. Magnuson Decl., ¶ 11. This technique requires creating some sort of path through the tissue to the reach the targeted site.[2]

According to the invention described and claimed in the Patents-In-Suit, the radiation source is introduced into the resection cavity. An expandable or inflatable device, such as a cage or balloon, is disposed at the end of the catheter to shape the resection cavity so that the radiation dose delivered to the diseased cells within the interstices of the tissue at the margins of the cavity is made more uniform. Three primary factors affect the amount of the absorbed dose: (1) distance of the tissue to be treated from the radiation source, (2) the presence of a radiation attenuating medium such as air or a saline solution; and (3) the use of radiation shielding.

The Patents-In-Suit use these factors, individually or in combination, to improve treatment by controlling the "radial absorbed dose profile," the "three-dimensional isodose profile," and the "isodose curves." The type of profile involves controlling the dose as a function of distance into the

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[2] Interstitial brachytherapy can be contrasted with traditional brachytherapy in which the radiation source is merely inserted into a natural body cavity like the bladder (intracavitary), into a body lumen like the urethra (intraluminal), or on the surface of the body (surface brachytherapy). Magnuson Decl., fn 1.

tissue; the latter two types involve controlling the shape of a surface defined by points receiving the same radiation dose. To control the radial absorbed dose profile, one may surround the radiation source with a radiation attenuating medium to minimize the ratio of the absorbed dose at the edge of the tumor cavity to the dose at the interstices to be treated. If the ratio is too high, then hot spots can form at the cavity edge that cause healthy tissue to necrose. Controlling the three-dimensional isodose profile or the isodose curve involves shaping the resected tumor cavity and/or adjusting the position of the radiation source relative to the cavity to create a desired isodose surface where all points on this surface receive substantially the same dose.

Having created the market for APBI through significant investment, Hologic relies on its exclusive patent rights to recoup that investment. Indeed, Hologic has defended these rights, suing Xoft, Inc. in 2006 in this Court for infringement of the '813 and '204 patents (the "Xoft Litigation"). *Xoft, Inc. v. Cytyc Corp.*, case no. 5:05-cv-05312-RMW filed April 27, 2007. Following a claim construction ruling in which this Court adopted most of Hologic's proposed claim constructions and rejected Xoft's § 112 invalidity defenses, the parties reached a settlement with Xoft taking a license to the patents at issue in that litigation.[3]

B. SenoRx Has Had No Presence In The Field Of Cancer Treatment

Until the release of the Contura MLB this January, SenoRx has not been a player in breast brachytherapy or, indeed, in any cancer treatment market. Founded in 1998, SenoRx's business has focused on breast biopsy equipment and related tools, *i.e.*, products directed to the diagnosis of cancer. Ex. D. Indeed, as recently as November 2007, SenoRx continued to describe itself as a company focused only on the diagnosis of breast cancer. *See* Ex. I [4]("SenoRx . . . develops, manufactures and sells minimally invasive medical devices used by breast care specialists for the diagnosis of breast cancer."). In those markets in which SenoRx has participated, it has a reputation in the industry as carving a niche as a low-price supplier, presumably to promote faster growth and penetration into its

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[3] Xoft targets a different market and has only minimal sales. For these reasons, among others, Xoft's presence has had no discernable effect on Hologic's sales.

[4] Unless otherwise noted, cited exhibits refer to exhibits attached to the Altemus Decl.

target markets. Magnuson Decl., ¶ 16. In any event, SenoRx is not, and has not been, a profitable company. SenoRx's most recent quarterly financial announcement showed a net loss of almost $2 million. Ex. I.

At the time Hologic filed the Complaint, SenoRx had not yet commercially launched the Contura MLB, offering the product to a limited number of clinical sites for "preference testing." In a December 20, 2007 press release, SenoRx noted that "key elements of our growth will be our Contura MLB radiation balloon, which we expect to transition from preference testing, currently expanded to 34 clinical sites, to full commercial launch in January 2008." Ex. J. Finally, on January 17, 2008, SenoRx announced that launch:

> SenoRx, Inc. (Nasdaq:SENO) today announced that it has launched Contura(tm), its Multi-Lumen Balloon (MLB) Catheter for delivering brachytherapy to the surgical margins following lumpectomy for breast cancer. The company had previously said that it intended to transition from user preference testing, which had expanded to 34 clinical sites by the end of 2007, to full commercial launch in January 2008.

Ex. E. The SenoRx press release touts the Contura as "one of a new class of devices which is designed to reduce radiation treatment time to five days from six to eight weeks" even though MammoSite has been doing just that since it was launched in mid-2002. *Id.* SenoRx also boasts that "the Contura MLB can play an important role in the shift from traditional whole breast radiation therapy to localized partial breast radiation therapy," even though MammoSite had pioneered that shift and has made considerable investments to drive that shift for over five years. *Id.* By violating Hologic's exclusive patent rights, SenoRx is poised to undercut Hologic's prices, to reap the benefits of Hologic's research and development investment, and to erode the market to the extent that Hologic cannot recoup that investment – an investment that SenoRx never had to make. Hologic therefore moves the Court for preliminary injunctive relief.

IV. ARGUMENT

Each of the four preliminary injunction factors favor Hologic: (1) Hologic will be able to show at trial that SenoRx's Contura MLB clearly infringes, *inter alia*, claim 36 of the '204 patent and claim

1 of the '142 patent;[5] (2) Hologic will be irreparably harmed in the absence of an injunction; (3) the threatened injury to Hologic outweighs the harm a preliminary injunction will cause SenoRx; and (4) the preliminary injunction will serve the public interest. *Abbott Labs. v. Andrx Pharms., Inc.*, 473 F.3d 1196, 1200-1201 (Fed. Cir. 2007); *Gillette Co. v. Energizer Holdings, Inc.*, 405 F.3d 1367, 1370 (Fed. Cir. 2005); *Hybritech, Inc. v. Abbott Labs.*, 849 F.2d 1446, 1451 (Fed. Cir. 1988).

A. Hologic Will Likely Succeed At Trial

Because each and every limitation of at least claim 36 of the '204 patent and claim 1 of the '142 patent is literally present in SenoRx's Contura MLB device, SenoRx infringes these claims.

1. This Court Has Already Construed Many Relevant Claim Terms In Hologic's Favor

This Court has already construed many of the claim terms likely to be at issue in the present case. In the Xoft Litigation, the claim construction issues for the '813 and '204 patents were fully briefed with expert opinions and argued to the Court, which included live expert testimony. This process culminated in the issuance of a Claim Construction Order in which Judge Whyte construed as a matter of law certain terms of the '813 and '204 patents, including a number of terms likely to be at issue in this litigation and relevant to the claims on which this Motion stands:[6]

Term or Phase	Judge Whyte's Construction
"interstitial"	Involving a surgically-created cavity in a body
"brachytherapy"	Radiation therapy delivered by a spatially-confined radioactive material inserted into the body at or near a tumor or other proliferative tissue disease site.
"interstitial brachytherapy"	(no construction necessary)

[5] The Contura MLB will be shown at trial to infringe multiple claims in each of the three Patents-In-Suit. In the interests of clarity and economy, however, and solely for purposes of this Motion, Hologic's infringement allegations are limited to these two claims.

[6] Judge Whyte has devoted significant judicial resources towards understanding the technology at issue, and Hologic has thus filed a Motion to Relate Cases with his chambers on January 9, 2008. That motion had not been acted upon as of the date of this filing. Ex. M.

Term or Phase	Judge Whyte's Construction
"inner spatial volume"	A region of space surrounded by an outer spatial volume and either enclosed by a polymeric film wall or defined by the outside surface of a solid radionuclide sphere.
"outer spatial volume"	A region of space defined by an expandable surface element and surrounding an inner "expandable surface element (no construction needed)"
"radiation source"	Radionuclide
"the inner and outer spatial volumes are configured to provide a minimum prescribed absorbed dose	(No construction necessary)
"a minimum distance outward from the outer spatial volume expandable surface"	(No construction necessary)
"controlled dose"	(no separate construction necessary)
"to reduce or prevent necrosis in healthy tissue proximate to the expandable surface"	(No separate construction necessary)
"providing a controlled dose at the outer spatial volume expandable surface to reduce or prevent necrosis in healthy tissue proximate to the expandable surface"	Controlling the ratio of the dose at the expandable surface of the outer spatial volume to the prescribed dose at the depth of interest in the target tissue so that the dose at the expandable surface is not so high that it lethally damages cells in healthy tissue in contact with the expandable surface.

For purposes of this Motion, the Court should rely on this Court's prior constructions of claim terms. *Nilssen v. Motorola*, 80 F. Supp. 2d 921, 924, fn.4 (N.D. Ill. 2004) (according respect to prior claim construction in a subsequent action against a different alleged infringer); *KX Industries v. Pur Water Purification Prods.*, 108 F. Supp.2d 280, 387 (D.Del. 2000) (deferring to prior claim construction in a subsequent action against a different alleged infringer to the extent the parties did not raise new arguments); *Texas Instruments, Inc. v. Linear Technologies Corp.*, 182 F. Supp. 2d 580, 585-590 (E.D.

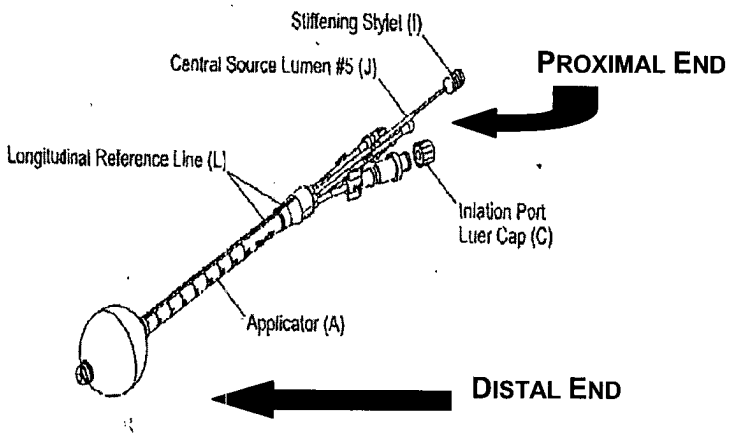
Tx. 2002) ("This Court does not disagree that the application of previously construed claims to independent defendants may be appropriate in some cases.").

Although the '142 patent was not construed by the Court during the Xoft Litigation, that patent is from the same family as the '204 and '813 patents, and contains the same or similar terms as those patents. Claim terms from the related '142 patent should, therefore, carry the same construed meaning as the identical terms in the '813 and '204 patents. *See Omega Engineering, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1334 (Fed. Cir. 2003) ("[W]e presume, unless otherwise compelled, that the same claim term in the same patent or related patents carries the same construed meaning."); *PCTEL, Inc. v. Agere Systems, Inc.*, 2005 WL 2206683, at *3 (N.D. Cal., Sept. 8 2005) ("[w]here Patents-In-Suit share the same disclosures, common terms are construed consistently across all claims in both patents"). Hologic believes that the meaning of each of the remaining unconstrued '142 claim terms is clear, and likely will not require construction. As such, those terms will likely be given their ordinary and customary meaning. *Phillips v. AWH Corp.*, 415 F.3d 1303, 312-14 (Fed. Cir. 2005) (*en banc*) ("[T]he words of a claim 'are generally given their ordinary and customary meaning,' . . . . In some cases, the ordinary meaning of patent claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words.").

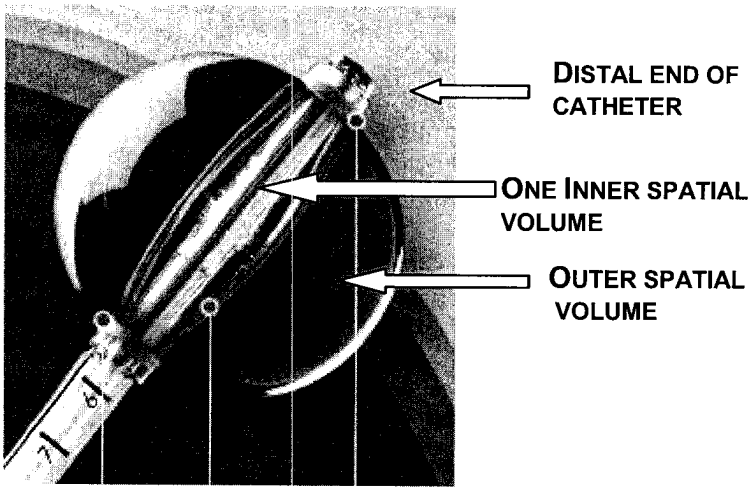
2. SenoRx's Contura MLB Infringes Claim 36 Of The '204 Patent.

Claim 36 of the '204 patent claims a brachytherapy device to deliver localized radiation to a cavity created by the excision of a tumor. The device is a catheter through which a radioactive source can be inserted into an expandable "balloon" at the other end of the catheter. Following tumor resection, the device is positioned within the surgically-created cavity and the balloon is expanded to fill the cavity, after which the radioactive source is inserted through the catheter and positioned within the balloon. Radioactivity is then emitted around that source so as to deliver in a predetermined fashion a controlled dose of radiation to the tissue surrounding the cavity. By controlling the dose of radiation, the physician can minimize damage to remaining healthy tissue near the cavity.

As established in the table below, the Contura MLB works identically and literally satisfies every limitation of claim 36 of the '204 patent.

Asserted Claim From The '204 Patent	SenoRx's Contura MLB Product Infringes The '204 Patent
36. An interstitial brachytherapy apparatus for delivering radioactive emissions to an internal body location comprising:	According to SenoRx's own product description, the Contura MLB is an interstitial brachytherapy apparatus designed to deliver radiation to the margins of the cavity remaining after surgical resection of breast cancer. Ex. A at Device Description; Ex. B at 2; Ex. E.
(a) a catheter body member having a proximal end and distal end;	Illustrations of the Contura MLB show a catheter with a proximal and distal end, with proximal ports for inflation and vacuum, as well as a distal "vacuum port." Ex. B at Figure 1 (shown below) "Radiation source lumens" are also run from the proximal end of the applicator into the treatment lumens at the distal end of the catheter. Ex. C; Altemus Decl. ¶ 4[7]  Figure 1: SENORX APPLICATOR

[7] An animated video of the Contura MLB from SenoRx's website describes the device as follows: "It's a balloon-based device. The balloon is implanted into the breast and it replaces the tissue that was removed by the surgeon. And the goal of the treatment is to treat the rind of the tissue surrounding the balloon. This animation provided to us by the makers of the device shows how it works. After the balloon is inserted into the breast, it is inflated and filled with a saline solution. Then radioactive seeds are sent through five separate channels inside the balloon. The dose is actually directed by where the seed sits within the balloon. So, having one offset from the center of the balloon allows us to pull that dose by leaving the seed in the balloon for a certain period of time – longer than the other side has it for an example. And that means the dosage of the radiation is concentrated on the tumor and doesn't burn the patient's skin. And if the skin was too close to channel 1, we might put the seed longer in channel 3 and 4 versus channel 1 to cool down that side of the dose." Altemus Decl., ¶ 4.

Asserted Claim From The '204 Patent	SenoRx's Contura MLB Product Infringes The '204 Patent
(b) an inner spatial volume disposed proximate to the distal end of the catheter body member	Each of the five treatment lumens inside the Contura MLB constitutes an inner spatial volume proximate to the distal end of the Contura MLB. Alternatively, the five treatment lumens and the area within the balloon between and surrounded by those lumens together define one inner spatial volume. Ex. A at Device Description; Ex. B at 2. An illustration of the Contura MLB shows the five treatment lumens within the balloon. Ex. C; Altemus Decl., ¶ 4 (showing animated schematic of one central and four "offset" lumen within the balloon). 

Asserted Claim From The '204 Patent	SenoRx's Contura MLB Product Infringes The '204 Patent
(c) an outer spatial volume defined by an expandable surface element disposed proximate to the distal end of the body member in a surrounding relation to the inner spatial volume;	According to SenoRx's marketing documents, the inflatable spherical balloon (an "expandable surface element") is located proximate to the vacuum port at the distal end of the applicator catheter. The circumference of the expandable balloon defines the outer spatial volume of the balloon applicator. The outer spatial volume surrounds and contains the inner spatial volume(s). Each of the five treatment lumens in the Contura MLB constitutes a separate inner spatial volume. Alternatively, the five treatment lumens and the area within the balloon between and surrounded by those lumens together define one inner spatial volume. Ex. A at Device Description; Ex. B at 2; Ex. C (magnified aspect view shown below); Altemus Decl., ¶ 4 (showing animated depiction of balloon expansion with subsequent increase in the size of the outer spatial volume).
(d) a radiation source disposed in the inner spatial volume;	Each radiation source ("radiation source wire") is inserted through a radiation source lumen into its respective central or curved treatment lumen (one "central lumen" and four "curved lumens"). As discussed above, these lumens constitute, individually or collectively, the claimed "inner spatial volume." Ex. A at Device Description; Ex. B at 2, 4; Ex. C; Altemus Decl., ¶ 4 (describing and showing animated depiction of the insertion of the radioactive seeds into the treatment lumens); Ex. E.

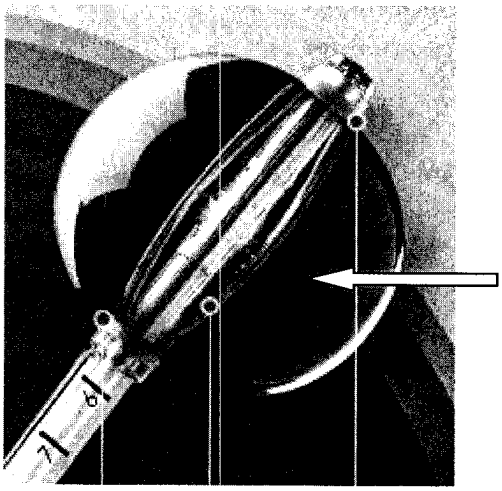
Asserted Claim From The '204 Patent	SenoRx's Contura MLB Product Infringes The '204 Patent
Wherein the inner and outer spatial volumes are configured to provide a minimum prescribed absorbed dose for delivering therapeutic effects to a target tissue, the target tissue being defined between the outer spatial volume expandable surface and a minimum distance outward from the outer spatial volume expandable surface, the apparatus providing a controlled dose at the outer spatial volume expandable surface to reduce or prevent necrosis in healthy tissue proximate to the expandable surface.	The Contura MLB is a balloon-based device which is inserted into a cavity remaining after the excision of a breast tumor. Once the balloon is in the cavity, the balloon is inflated with a contrast medium or saline (injected through the inflation port) to conform the cavity to the shape of the balloon. Parameters of the balloon size and location are adjusted to conform the surgical margin of the tissue to the shape of the outer volume of the balloon. Insertion of radiation source wires into selected treatment lumens for prescribed lengths of time controls the dose of radiation targeting the tissue, thereby preventing damage to healthy tissue proximate to the surface of the balloon. Ex. B at 4; Ex. C; Altemus Decl., ¶ 4 (showing animated depiction of the insertion and use of the Contura MLB device); Ex. E. This is specifically explained in the SenoRx video described in Altemus Decl., ¶ 4.

3. SenoRx's Contura MLB Infringes Claim 1 Of The '142 Patent.

Claim 1 of the '142 patent claims a brachytherapy device designed to deliver localized radiation to a cavity created by the excision of a tumor. The device is a catheter through which a radioactive source can be inserted into the expandable "balloon" at the other end of the catheter. Following resection of a tumor, the device is positioned within the surgically-created cavity and the balloon is expanded to fill the cavity, after which the radioactive source is inserted through the catheter and positioned asymmetrically (*e.g.*, off-center) within the balloon. Radioactivity is then emitted in three dimensions around that off-center source so as to deliver, in a predetermined fashion, a controlled dose of radiation that asymmetrically targets the tissue remaining at the surgical margins of the cavity. By controlling and shaping the dose of radiation targeting various portions of the cavity, the physician can minimize damage to remaining healthy tissue near the cavity.

As established in the table below, the Contura MLB works the same way and literally satisfies every limitation of claim 1 of the '142 patent.

Asserted Claim From The '142 Patent	SenoRx's Contura MLB Product Infringes The '142 Patent
1. An interstitial brachytherapy apparatus for treating target tissue surrounding a surgical extraction comprising:	The Contura MLB is an interstitial brachytherapy apparatus designed to deliver localized radiation to the margins of the cavity remaining after surgical resection of breast cancer. Ex. A at Device Description; Ex. B at 2; Ex. E.

Asserted Claim From The '142 Patent	SenoRx's Contura MLB Product Infringes The '142 Patent
an expandable outer surface defining a three-dimensional apparatus volume configured to fill an interstitial void created by the surgical extraction of diseased tissue and define an inner boundary of the target tissue being treated;	The outer surface of the inflatable spherical Contura MLB (an "expandable outer surface") defines the three-dimensional apparatus volume that fills the resection cavity. The expanded balloon conforms the cavity to the balloon shape and thereby defines the inner boundary of target tissue along the cavity wall that is being treated. Ex. A at Device Description; Ex. B at 2, 4; Altemus Decl., ¶ 4 (showing expansion of balloon with subsequent increase in the three-dimensional apparatus volume); Ex. F. An illustration of the Contura MLB shows the three-dimensional apparatus volume defined by the expandable polyurethane balloon to be inflated in the resection cavity. Ex. C. 

Asserted Claim From The '142 Patent	SenoRx's Contura MLB Product Infringes The '142 Patent
a radiation source disposed completely within the expandable outer surface	Each radiation source ("radiation source wire") is inserted through a radiation source lumen in the Contura MLB into its respective central or curved treatment lumen. Ex. A at Device Description; Ex. B at 2, 4 ; Altemus Decl., ¶ 4 (showing animated depiction of and describing insertion of the radioactive seeds into the treatment lumens); Ex. E. An illustration of the Contura MLB shows the five treatment lumens located within the center of the expandable outer surface of the balloon. Ex. C.
and located so as to be spaced apart from the apparatus volume, the radiation source further being asymmetrically located and arranged within the expandable surface to provide predetermined asymmetric isodose curves with respect to the apparatus volume.	Each radiation source ("radiation source wire") is inserted through a radiation source lumen into its respective central or curved treatment lumen. All of the treatment lumens are spaced apart from the apparatus volume (*e.g.*, not touching the interior surface of the expandable surface of the balloon) and are arranged asymmetrically in a manner predetermined by the treating physician so as to irradiate a select asymmetric area of tissue. One way in which this asymmetric dosing is achieved is by varying the duration of time radioactive seeds reside within selected treatment lumens. Commercially available treatment planning software is used by the physician to determine the appropriate parameters of the dosing for optimized radiation delivery of a prescribed dose to the targeted treatment volume. The optimized radiation delivery is reflected in asymmetric isodose curves. *See* Ex. A at Device Description; Ex. B at 2, 4; Ex. C (magnified aspect view shown below); Altemus Decl., ¶ 4 (describing insertion of the radioactive seeds into the treatment lumens, showing animated depiction of the asymmetric treatment

Asserted Claim From The '142 Patent	SenoRx's Contura MLB Product Infringes The '142 Patent
	achieved by insertion of radioactive seeds into a select treatment lumen, and showing animated depiction of asymmetric isodose curves).

Based on SenoRx's publicly available materials, there can be no serious dispute that the Contura MLB literally practices each element of the claims at issue in this Motion.[8]

B. Hologic Will Suffer Irreparable Injury If SenoRx Is Permitted To Make Infringing Sales Pending Trial

Once a showing of likelihood of success is made, a movant is entitled to a presumption of irreparable harm. *See Abbott Labs, v. Andrx Pharms., Inc.*, 452 F.3d 1331, 1347 (Fed. Cir. 2006) (presumption of irreparable would have applied if Abbot had established a likelihood of success on the merits); *see also Docusign, Inc. v. Sertifi, Inc.*, 468 F. Supp. 2d 1305, 1309 n.6 (W.D. Wash. 2006) ("*Abbott*, which came after *eBay*, assumed (without deciding) that such a presumption was still appropriate in the preliminary injunction context, where a strong showing of likely infringement was made."); *Christiana Industries v. Empire Electronics*, Inc., 443 F. Supp. 2d 870, 884 (E.D. Mich. 2006) ("Plaintiff argues, and this Court agrees, that eBay did not invalidate the presumption [of irreparable harm]."); *PHG Techs. v. Timemed Labeling Sys.*, 2006 U.S. Dist. LEXIS 66828, at *65 (M.D. Tenn. Sep. 18, 2006) ("having established the first factor of likelihood of success on the merits PHG is entitled to a rebuttable presumption of irreparable harm").

Hologic need not rely exclusively on this presumption, however, as SenoRx's market entry may irreparably harm Hologic in at least five specific ways. *First,* Hologic believes that SenoRx's

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[8] Hologic's patents are entitled to a statutory presumption of validity. 35 U.S.C. § 282. Consequently, SenoRx bears the burden of establishing invalidity of each patent claim by clear and convincing evidence. *Nystrom v. Trex Co.*, 424 F.3d 1136, 1149 (Fed. Cir. 2005), *cert. denied*, 547 U.S. 1055 (2006). Unless SenoRx mounts a serious challenge to the validity or enforceability of the patents in suit – something Xoft was unable to do – the likelihood of success factor is established by a showing of likelihood of infringement.

primary business strategy is to poach MammoSite customers by underpricing Hologic Redacted and Hologic's potential injury therefrom is both irreparable and difficult to calculate. Magnuson Decl., ¶ 19. Of course, SenoRx is only capable of engendering this price erosion because it never had to invest the millions of dollars that Hologic invested to create the market. Magnuson Decl., ¶ 20. *Second,* given SenoRx's financial results, it is doubtful that SenoRx would be able to compensate Hologic for the damage that SenoRx causes during litigation, even if that damage is readily calculable. *Third*, SenoRx's market presence will decrease Hologic's market share, revenue, and profits in the burgeoning APBI market. Magnuson Decl., ¶ 20. *Fourth*, SenoRx's market presence will harm Hologic's reputation as an innovator and market leader. Magnuson Decl., ¶ 18. *Fifth*, unproven, off-label treatments of patients with Contura MLB – which SenoRx is promoting – may irretrievably damage the reputation of APBI as a treatment modality. Magnuson Decl., ¶ 23.

1. SenoRx's Entry Will Likely Change The APBI Market

Redacted

Such price erosion in combination with a strategy to target existing MammoSite customers, rather than expand the market, is the very definition of irreparable harm. *See Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1368 (Fed. Cir. 2001) ("Given the testimony of the likelihood of price erosion and loss of market position without corresponding market expansion from the introduction of Roxane's product, we see no deficiency in the district court's finding of irreparable harm."). *See also Verizon Servs. Corp. v. Vonage Holdings Corp.*, 503 F.3d 1295, 1310 (Fed. Cir. 2007) (affirming grant of preliminary injunction in light of "evidence of price erosion"); *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1381 (Fed. Cir. 2006) (price erosion is a "form of irreparable harm"); *Canon Inc. v. GCC Int'l, Ltd.*, 450 F. Supp. 2d 243, 255 (S.D.N.Y. 2006) (granting

motion for preliminary injunction because "[c]ompetition from defendants would likely lead to significant price erosion") *aff'd*, No. 2006-1615, 2007 U.S. App. LEXIS 26584 (Fed. Cir. 2007).

More generally, because Hologic is the only current supplier of radionuclide-based balloon applicators for breast brachytherapy, Hologic is likely to lose both market share and profits once SenoRx enters the market. Magnuson Decl., ¶¶ 18-20. And since SenoRx has only now begun to commercialize its product, Hologic – and the Court – may well be in the position of having to speculate as to the nature and magnitude of Hologic's lost profits resulting from SenoRx's sales. Magnusson Decl., ¶¶ 20, 21. Given the certain, yet difficult to quantify damage to Hologic, monetary damages will not suffice and an injunction is warranted. *Rosen Entm't Sys.*, 343 F. Supp. 2d 908, 915 (C.D. Cal. 2004) (noting that "damage computation difficulty" is a factor supporting injunctive relief).

2. SenoRx's Market Presence Will Decrease Hologic's Market Share, Revenue, And Profits In The Burgeoning APBI Market.

When a company like Hologic pioneers an invention in the marketplace, "irreparable harm flows from a competitor's attempts to usurp the pioneering company's market position and goodwill." *800 Adept, Inc. v. Murex Securities, Ltd.*, 2007 WL 1101238, * 6 (M.D. Fla. 2007). Hologic spent years developing the technology underlying the MammoSite, only to have SenoRx market its infringing Contura MLB to current MammoSite users. Magnuson Decl., ¶¶ 10, 23. SenoRx threatens to make an immediate impact in the high-growth market; again, a prototypical instance of irreparable harm. *TiVo Inc. v. Echostar Communicators Corp.*, 446 F. Supp.2d 664, 669-670 (E.D. Tex. 2006) ("Defendants compete directly with Plaintiff-Defendants [and] market their infringing products to potential DVR customers as an alternative to purchasing Plaintiff's DVRs. The availability of the infringing products leads to loss of market share for Plaintiff's products. Loss of market share in this nascent market is a key consideration in finding that Plaintiff suffers irreparable harm – Plaintiff is losing market share at a critical time in the market's development, market share that it will not have the same opportunity to capture once the market matures.").

3. SenoRx Will Likely Be Unable To Pay Damages

SenoRx is not profitable. Last quarter it reported a net loss of almost $2 million. Ex. I. In the absence of a preliminary injunction, SenoRx could be found to owe damages for over two years of

infringing activity, assuming that this case proceeds to trial at the typical rate for this Court. (Ex. K) MammoSite sales totaled $28.5 million in 2006 and $34.9 million in 2007, and are expected to continue to grow. Magnuson Decl., ¶ 12. Any meaningful market penetration by SenoRx could result in a verdict on the order of tens of millions of dollars. It would appear highly unlikely that SenoRx could afford such an award. Thus, absent a preliminary injunction, Hologic "will have no substantive relief." *MGM Studios, Inc. v. Grokster, Ltd.*, 518 F. Supp. 2d 1197 (C.D. Cal. 2007) ("[I]n another copyright infringement case, the district court found that the harm from infringement 'will not be remedied by a damage award that may or may not be collectible.'. The rationale in such cases must be that an award of monetary damages will be meaningless, and the plaintiff will have no substantive relief, where it will be impossible to collect an award for past and/or future infringements perpetrated by a defendant.") (citing *Lava Records LLC v. Ates*, 2006 U.S. Dist. LEXIS 46683, at *3 (W.D. La. July 11, 2006)); *Rosen Entm't Sys. v. Vision*, 343 F. Supp. 2d 908, 915 (C.D. Cal. 2004) (noting that "infringer inability to pay damage award" is a factor supporting irreparable harm).

4. SenoRx's Market Presence Threatens Hologic's Reputation As An Innovator

By infringing Hologic's patented technology, SenoRx positioned itself to compete with Hologic in the manufacture and sale of balloon applicators for APBI. In addition to SenoRx, several competitors such as North American Scientific Inc., and BioLucent (now Cianna Medical), are currently developing balloon applicators for breast brachytherapy. Magnuson Decl., ¶ 13. If SenoRx suffers no adverse consequences from its continued infringement, then that will send a message to other potential competitors that they can infringe as well, knowing that no consequences will follow. Magnuson Decl., ¶ 22. *See Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corporation*, 106 F. Supp. 2d 696, 703 (D.N.J. 2000) (failure to issue an injunction may damage a company's reputation as competitors may perceive that company as unable to enforce the exclusivity of its patent rights despite having proven liability and validity).

5. SenoRx's Infringing Presence In The Market Damages The Reputation of APBI As An Effective Treatment Modality

Hologic is concerned that SenoRx is promoting its Contura MLB in a manner inconsistent with the FDA-approved labeling of that product without any clinical data to support those promotions. In the press release announcing the FDA clearance of the Contura MLB, SenoRx stated: "Certain patients who are presently candidates for balloon therapy are currently excluded because of the location of the lesion relative to their breast size. Our multi-lumen approach offers a solution to this problem." Ex. N; Magnuson Decl., ¶ 23. Similarly, the press release announcing the launch of the Contura MLB on January 17, 2008 contains a similar statement: "Some patients who are presently candidates for balloon therapy are currently excluded because of the location of the lesion and their breast size. Contura's advanced multi-lumen design may address this issue for certain patients." Ex. E. These statements are disturbing because the indications and warnings of the Contura MLB are identical to those of the MammoSite. Indeed that identity was the basis for FDA's clearance of the Contura MLB – to avoid conducting its own clinical studies, SenoRx told the FDA that the Contura MLB was equivalent to the MammoSite. Magnuson Decl., ¶ 23. There is no basis, therefore, for SenoRx's assertion that the Contura MLB can treat a different patient population than the MammoSite. And Hologic is unaware of any clinical studies to support such an assertion. The promotion of SenoRx's Contura system with the potential for patient harm, and the absence of safety and effectiveness data, may tarnish medical opinion regarding the use of interstitial brachytherapy procedures as a whole, including MammoSite.

* * *

All these factors support a finding that Hologic would be irreparably harmed absent preliminary injunctive relief.

C. The Balance of Hardships Favors Entry of the Injunction

Infringers (such as SenoRx) who have apparently decided to expand their business based on infringing activities cannot complain that the entry of an injunction to enforce the patent laws will harm that business. As the Federal Circuit admonished, "[o]ne who elects to build a business on a product found to infringe cannot be heard to complain if an injunction against continuing infringement

destroys the business so elected." *Windsurfing Int'l, Inc. v. AMF, Inc.*, 782 F.2d 995, 1003, n. 12 (Fed. Cir. 1986); s*ee also Boehringer Ingelheim,* 106 F.Supp.2d at 707.

In any event, SenoRx cannot claim significant harm from an injunction. The company has been in existence since 1998 providing a broad range of products, none of them for cancer treatment. An injunction would merely preserve the status quo, leaving SenoRx no worse off than it was just a few weeks ago. Hologic, on the other hand and as discussed, would suffer significant irreparable injury to its business, its future opportunities, and general reputation in the health care and patient communities. The balance of hardships factor thus weighs in favor of granting a preliminary injunction.

D. A Preliminary Injunction Will Serve The Public Interest

An injunction in this case well serves the public interest. "The public has an interest in maintaining a strong patent system." *TiVo*, 446 F. Supp. 2d at 670. In light of this policy, the Federal Circuit has stressed that "the focus of the district court's public interest analysis should be whether there exists some critical public interest that would be injured by the grant of [injunctive] relief." *Hybritech,* 849 F.2d at 1458. There is no possibility of any such harm, as Hologic has the capacity to manufacture and sell several times the quantity of MammoSite applicators currently being sold. Magnuson Decl., ¶ 24. There will be no adverse effect on the public's access to the patented technologies at issue. Indeed, with SenoRx's promotion of the Contura MLB for unsupported, off-label uses, the reputation of brachytherapy as a whole could be tarnished, resulting in fewer women electing to undergo post-lumpectomy treatment and thereby increasing the associated cancer recurrence rate. The public would be well served by a preliminary – and eventually permanent – injunction.

* * *

In summary, all four *eBay* factors weigh in favor of granting a preliminary injunction. Hologic thus respectfully requests this Court grant entry of preliminary injunction against plaintiff SenoRx with respect to claim 36 of the '204 patent and claim 1 of the '142 patent.

V. CONCLUSION

For the reasons stated above, Hologic respectfully asks that the Court enjoin SenoRx and those acting in concert with SenoRx from further infringement of claim 36 of the '204 patent and claim 1 of the '142 patent.

Dated: February 6, 2008

By: /s/
Katharine L. Altemus

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Attorneys for Plaintiff
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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

HOLOGIC, INC., CYTYC CORPORATION, and HOLOGIC LP, Plaintiffs, vs. SENORX, INC., Defendant.	Case No. C08-00133-MEJ **DECLARATION OF KATHARINE L. ALTEMUS IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION** **Date: March 20, 2008** **Time: 10:00a.m.** **Courtroom: B, 15th floor** **Judge: Hon. Maria-Elena James**

I, Katharine L. Altemus, declare that I am an associate in the law firm Howrey LLP and a member of the Bar of this court, and I serve as one of the outside counsel for Hologic, Inc., Cytyc

Corporation and Hologic LP. The following declaration is based on my personal knowledge, and if called upon to testify, I could and would competently testify as to the matters set forth herein.

1. Attached hereto as Exhibit A is a true and correct copy of correspondence from Nancy Brogdon of the Food and Drug Administration ("FDA") to SenoRx, Inc. ("SenoRx), dated May 18, 2007, and posted on the FDA website at *http://www.fda.gov/cdrh/pdf7/K071229.pdf*.

2. Attached hereto as Exhibit B is a true and correct copy of the Instructions for Use for the SenoRx Multi-Lumen Balloon Source Applicator for Brachytherapy.

3. Attached hereto as Exhibit C is a true and correct copy of an illustration posted on the SenoRx website at *http://www.senorx.com/images/SNRX_7000_conturads_7.jpg*.

4. A publicly available news report posted on the worldwide web (and accessible via a web link posted on the SenoRx website) describes the use of SenoRx's Multi-Lumen Balloon Applicator to treat a patient in Arizona diagnosed with breast cancer, and includes an animation provided by SenoRx to explain how the Contura device is inserted to deliver radiation treatment. Within the report, the device is described as follows: "It's a balloon-based device. The balloon is implanted into the breast and it replaces the tissue that was removed by the surgeon. And the goal of the treatment is to treat the rind of the tissue surrounding the balloon. This animation provided to us by the makers of the device shows how it works. After the balloon is inserted into the breast, it is inflated and filled with a saline solution. Then radioactive seeds are sent through five separate channels inside the balloon. The dose is actually directed by where the seed sits within the balloon. So, having one offset from the center of the balloon allows us to pull that dose by leaving the seed in the balloon for a certain period of time – longer than the other side has it for an example. And that means the dosage of the radiation is concentrated on the tumor and doesn't burn the patient's skin. And if the skin was too close to channel 1, we might put the seed longer in channel 3 and 4 versus channel 1 to cool down that side of the dose." The video news report is posted online at *http://www.myfoxphoenix.com/myfox/pages/Home/Detail;jsessionid=18E5571CEC66E18169DF1494828ED0A5?contentId=5126377&version=1&locale=EN-US&layoutCode=VSTY&pageId=1.1.1&sflg=1*. A web link to this news report (entitled "First

Contura MLB used in Chandler, AZ") is accessible on the SenoRx website at *www.SenoRx.com*. A true and correct copy of the video news report will be produced on CD should the Court so request.

5. Attached hereto as Exhibit D is a true and correct copy of a SenoRx webpage, posted as *http://www.senorx.com/aboutsenrx.asp*.

6. Attached hereto as Exhibit E is a true and correct copy of a SenoRx January 17, 2008 press release posted at *http://www.senorx.com/siteadmin/files/SenoRxLaunchesContura.pdf*.

7. Attached hereto as Exhibit F is a true and correct copy of a SenoRx webpage, posted at *http://www.senorx.com/teatment.asp*.

8. Attached hereto as Exhibit G is a true and correct copy of a webpage posted on the University of Washington Medical Center website at *http://www.uwmedicine.org/PatientCare/MedicalSpecialties/SpecialtyCare/UWMEDICALCENTER/Cancer/SpecialtyServices/brachytherapypatientinfo.htm.*

9. Attached hereto as Exhibit H is a true and correct copy of information posted electronically at *http://www.mammosite.com/breast-lumpectomy/how-it-works.cfm*.

10. Attached hereto as Exhibit I is a true and correct copy of information posted electronically at *http://www.senorx.com/siteadmin/files/SenoRxAnnouncesThirdQuarter2007Results.pdf*.

11. Attached hereto as Exhibit J is a true and correct copy of a SenoRx December 20, 2007 press release posted on the SenoRx website at *http://www.senorx.com/siteadmin/files/SenoRxProvides2008RevenueEstimate.pdf*.

12. Attached hereto as Exhibit K is a true and correct copy of "Table C-10. U.S. District Courts—Median Time Intervals From Filing To Trial of Civil Cases in Which Trials Were Completed, by District, During the 12-Month Period Ending September 30, 2006", published by the Office of Judges Programs (Statistics Division) of the Administrative Offices of the United States Courts at *http://www.uscourts.gov/judbus2006/appendices/c10.pdf*.

13. Attached hereto as Exhibit L is a true and correct copy of Judge Ronald M. Whyte's April 27, 2007 Claim Construction Order in the Northern District of California action *Xoft, Inc. v. Cytyc Corp.*, case no. 5:05-cv-05312-RMW.

14. Attached hereto as Exhibit M is a true and correct copy of Cytyc Corp.'s Administrative Motion Under Civil Local Rule 12(B) To Consider Whether Cases Should Be Related, filed January 9, 2008 in the Northern District of California action *Xoft, Inc. v. Cytyc Corp.*, case no. 5:05-cv-05312-RMW.

15. Attached hereto as Exhibit N is a true and correct copy of a SenoRx May 23, 2007 press release posted on the SenoRx website at *http://www.senorx.com/siteadmin/files/SenoRAnnounces510_k_ClearanceforMulti-LumenRadiationBalloon.pdf.*

I declare under penalty of perjury that the foregoing is true and correct.

By: /s/ Katharine L. Altemus
Katharine L. Altemus

Executed on February 6, 2008

East Palo Alto, California

K071229

SENORX

MAY 18 2007

5. 510(K) SUMMARY

Prepared date	April 20, 2007
510(k) owner	**SenoRx, Inc.** 11 Columbia Aliso Viejo, CA 92656 P. 949.362.4800 F. 949.362.3200
Contact person	Eben Gordon
Device name	SenoRad Multi-Lumen Balloon Source Applicator for Brachytherapy
Common name	Multi-lumen balloon source applicator
Classification name	Remote controlled radionuclide source applicator
CFR classification	21 CFR 892.5700 90 JAQ
Predicate device	Adjustable Multi-Catheter Source Applicator (K062241) MammoSite Radiation Therapy System (K041929)
Decision date	11/9/2006 (K062241) 8/26/2004 (K041929)
Device description	The SenoRad applicator consists of a multi-lumen catheter connected to an inflatable spherical balloon that can be attached to commercially available High Dose Rate remote afterloader equipment for passage of the radiation source delivery wire. Five radiation source wire lumens are provided; one central lumen located along the long axis of the applicator and four curved lumens symmetrically offset from the central lumen. The balloon is inflated to a 4 or 5 cm spherical shape by a controlled volume injection of physiological saline to approximately 32 or 55 ml, respectively.
Indications for use	The SenoRad Multi-Lumen Balloon Source Applicator for Brachytherapy is intended to provide brachytherapy when the physician chooses to deliver intracavitary radiation to the surgical margins following lumpectomy for breast cancer.
Summary of substantial equivalence	Extensive preclinical testing was conducted to evaluate and characterize the performance of the SenoRad Multi-Lumen Balloon Source Applicator. Preclinical studies conducted included in vitro laboratory studies to demonstrate that the SenoRad applicator performed as intended under simulated use conditions. Biocompatibility testing was performed to

SENORX

demonstrate that the materials meet ISO 10993-1 requirements. The dosimetry of the SenoRad applicator was characterized. Based on these findings, it was concluded that the SenoRad applicator could deliver an equivalent radiation dose as the current brachytherapy applicators.

The SenoRad applicator has the following similarities to the previously cleared predicate devices: same indications for use; same intended use; same intended treatment site; same operating principle; same technological characteristics; equivalent dosimetric characteristics; and same sterilization method. The materials of construction vary in a manner that has no impact on device safety.

In summary, the SenoRad Multi-Lumen Balloon Source Applicator as described in this submission is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAY 18 2007

SenoRx, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K071229
Trade/Device Name: SecoRad Multi-Lumen Ballon Source Applicator for Brachytherapy
Regulation Number: 21 CFR §892.5700
Regulation Name: Remote controlled radio-nuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: May 2, 2007
Received: May 3, 2007

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. INDICATIONS FOR USE

510(k) Number (if known): K071229

Device Name: _____ SenoRad Multi-Lumen Balloon Source Applicator for Brachytherapy _____

Indications for Use:

The SenoRad Multi-Lumen Balloon Source Applicator for Brachytherapy is intended to provide brachytherapy when the physician chooses to deliver intracavitary radiation to the surgical margins following lumpectomy for breast cancer.

Prescription Use ___X____ AND/OR Over the Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K071229

Page __ of ___

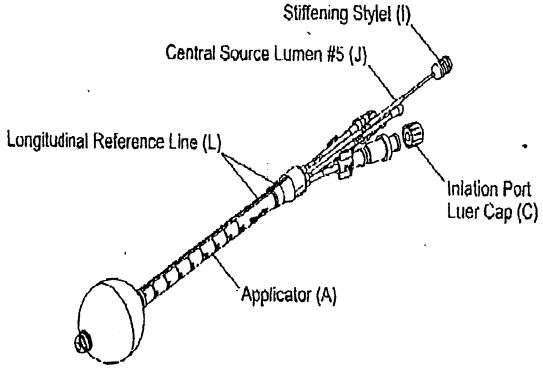

Figure 1: SENORX APPLICATOR

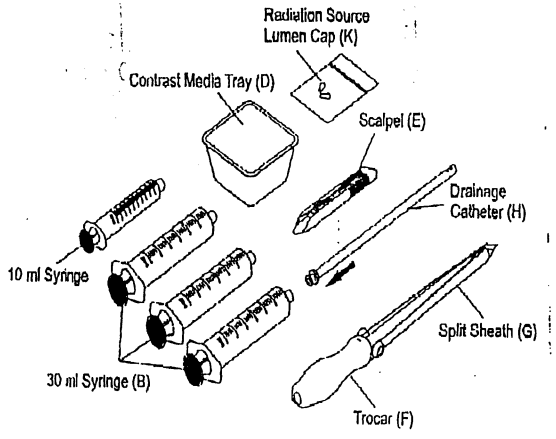

Figure 2: ACCESSORIES

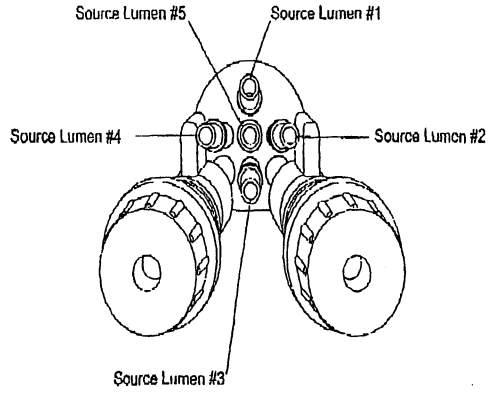

Figure 3: SOURCE WIRE LUMEN ORIENTATION

This product is covered by one or more of the following U.S. Patents: 6,923,754; 6,955,641; 7,241,178. Other domestic and foreign patents pending.

EXPLANATION OF SYMBOLS ON THE PACKAGE

REF	Catalogue Number
	Use by Date
LOT	Lot Number
CONT	Contents
STERILE R	Sterile (Gamma radiation)
	Attention, See Instructions for Use
	Do Not Reuse
	Upper Temperature Limit
	Keep away from sunlight
	Keep dry

SenoRx Inc.
Aliso Viejo, California
USA

SENORX

MULTI-LUMEN BALLOON SOURCE APPLICATOR FOR BRACHYTHERAPY

INSTRUCTIONS FOR USE

MODELS

B001-45
B011-45

IU0093 Rev. B
ECO 3776

SENORX

MULTI-LUMEN BALLOON SOURCE APPLICATOR FOR BRACHYTHERAPY

Caution: **Federal (USA) law restricts this device to sale by or on the order of a physician.**

DESCRIPTION

The SenoRx applicator consists of a multi-lumen catheter attached to an inflatable spherical balloon (Figure 1). Lumens are provided for attachment to commercially available HDR (High Dose Rate) remote afterloader equipment for passage of the radiation source delivery wire. Five radiation source wire lumens are provided; one central lumen located along the long axis of the applicator and four curved lumens symmetrically offset from the central lumen. A removable stiffening stylet is positioned in the central lumen. Two proximal ports are also provided with Luer-type connectors for balloon inflation/deflation and for application of intracavitary vacuum.

The SenoRx Multi-Lumen Balloon Accessories provided for introduction and deployment include: trocar with split sheath, drainage catheter, three, 30 ml and one, 10 ml inflation syringes, #11 scalpel, contrast media tray, radiation lumen caps and labels (Figure 2).

The SenoRx applicator model B001-45 is recommended for use with VariSource and Nucletron HDR afterloader equipment while model B011-45 is recommended for use with GammaMed afterloaders.

Warning: The safety and effectiveness of the SenoRx Applicator as a replacement for whole breast irradiation in the treatment of breast cancer has not been established.

INDICATIONS FOR USE

The SenoRx Multi-Lumen Balloon is intended to provide brachytherapy when the physician chooses to deliver intracavitary radiation to the surgical margins following lumpectomy for breast cancer.

CONTRAINDICATIONS

- The applicator is not intended for use in cavities that are too small, too large and/or of shapes unable to conform to an approximately spherical, 4 to 5 cm diameter SenoRx balloon.
- The applicator is not intended for use in patients with unusual anatomy including a highly curved rib structure and/or unequal amounts of tissue surrounding the cavity that may cause the SenoRx balloon to be asymmetrical.

WARNINGS

- Use caution when positioning the trocar tip near the chest wall or skin margin to avoid unintended tissue damage.
- Do not fill the Applicator with more than 58 ml of fluid as overfilling may result in balloon rupture and/or device failure.
- The Applicator must be pre-tested before implantation. Do not use the balloon if it is not approximately spherical and/or any leakage is detected.

- The breast cavity must be imaged before implantation to insure the applicator will fit appropriately. Do not use if the cavity is too small or if a skin surface to balloon surface distance of less than 5 mm will result.
- To insure appropriate treatment dose distribution, the SenoRx balloon must be imaged prior to delivering each fraction of radiation to confirm correct position, volume, skin spacing and conformance.
- If excessive resistance is encountered when attempting to remove the SenoRx applicator from the patient, surgical removal is recommended.
- Contrast media concentrations of less than 10% are recommended to prevent dose attenuation.
- Non-ionic contrast media is recommended for patients who are allergic to iodine-based agents.

PRECAUTIONS

- The SenoRx applicator must be used only by physicians trained in catheter implantation, radiation treatment planning and delivery.
- Metal vascular and marking clips should not be used during the lumpectomy procedure to prevent potential abrasion or puncture of the SenoRx™ balloon. Care should also be taken to direct suture knots and tails away from the cavity and whenever possible position tissue between the potential balloon surface and the tails.
- Store the SenoRx applicator at room temperature (20 to 25°C).
- Care must be taken when handling and manipulating the SenoRx balloon to prevent damage and foreign material contamination of the balloon surface.
- A scalpel should be used to incise the skin prior to inserting the trocar tip.
- Do not inject fluids into the Vacuum Port.
- Replace Luer caps and radiation lumen caps after use.
- Only clinical personnel trained in the operation of HDR afterloaders should deliver radiation using the SenoRx applicator.
- Verify that the appropriate afterloader connectors are available and function with the SenoRx applicator prior to treatment.
- Be sure that the SenoRx applicator is as straight as possible and free of sharp bends and kinks prior to connecting to the HDR afterloader.
- Inspect package before use. Discard if seal is compromised or packaging is damaged.

COMPLICATIONS

Complications that may be associated with the use of the SenoRx applicator are the same as those associated with the use of similar devices. These may include: erythema, catheter site drainage, breast pain, ecchymosis, breast fibrosis, telangiectasia, breast induration, breast seroma, breast edema, dry desquamation, dry skin, skin discoloration, parasthesia, axillary pain, fatigue, pruritis, breast retraction, nausea, skin irritation, moist desquamation, hematoma, rash, asymptomatic fat necrosis, breast infection, breast blister and lymphedema.

HOW SUPPLIED

The SenoRx applicator and accessories are provided sterile and are intended for single patient use only.

DIRECTIONS FOR USE

- PLACEMENT - Refer to Figures 1 & 2

1. Use ultrasound to identify the lumpectomy cavity.
2. Open the SenoRx applicator sterile package and remove the Applicator (A) and one 30 ml Syringe (B). Remove the Inflation Port Luer Cap (C) and inject 58 ml of sterile saline into the Applicator and inspect for leaks and spherical symmetry. Discard Applicator if defective. Withdraw saline from balloon.
3. Prepare a maximum 10% contrast media/sterile saline solution in the Tray (D) provided.
4. Determine the desired point on the breast surface for the insertion of the SenoRx applicator. Inject appropriate anesthetic to the skin and pathway to the lumpectomy cavity. Make a skin incision with the scalpel at the insertion point of sufficient length to fully insert the Trocar (F) tip. Dilate the skin incision, if desired. Advance the Trocar with Split Sheath (G) into the cavity. Remove the Trocar.
5. Attach a 30 ml syringe to the Drainage Catheter (H) and drain any fluids within the cavity by inserting the Drainage Catheter through the Split Sheath and suctioning. Remove the Drainage Catheter.
6. Insert the Applicator through the Split Sheath into the cavity. Remove the Sheath.
7. Remove the stiffening Stylet (I) from the Central Source Lumen (J). Attach a red radiation source lumen Cap (K).
8. Using the syringes provided, inflate the Applicator balloon with the contrast media solution to the desired fill volume.

Desired balloon diameter	Approximate balloon fill volume
4 cm	33 ml
5 cm	58 ml

9. Replace the Luer Cap on to the Inflation Port.
10. Use ultrasound to confirm appropriate placement, volume and cavity conformance. Fluid and air surrounding the Applicator balloon may be aspirated with a 30 ml Syringe attached to the Vacuum Port (L). The volume of the balloon may be adjusted through the Inflation Port (C). Replace Luer Caps when finished.
11. Apply a surgical dressing to the exit site with the catheter positioned to minimize bending.
12. Record the final balloon fill volume on the Labels provided and attach to the patient's chart.

- RADIATION DELIVERY - Refer to Figure 3

1. CT imaging should be used in conjunction with commercially available treatment planning software to determine the appropriate source lumens, source dwell positions and dwell times for optimized radiation delivery of a prescribed dose to the targeted treatment volume.
2. Verify correct balloon position, volume, skin spacing and conformance using imaging prior to delivery of each fraction of radiation.
3. The SenoRx applicator red-capped, radiation source wire lumens are numbered '1', '2', '3', '4' and '5' and positioned as shown in Figure 3. Lumen number '1' corresponds to the offset lumen closest and parallel to the longitudinal radiopaque line (M) along the outside of the catheter. Lumen number '5' corresponds to the central lumen. Remove the red caps and use commercially available connectors to attach the source lumens to the afterloader. After each treatment replace the red caps.

- REMOVAL

Remove the SenoRx applicator by first attaching a syringe to the Inflation Port and deflating the balloon and then simultaneously rotating and pulling (unscrewing) the catheter from the cavity.

Contura™
Multi-Lumen Balloon • MLB

Expanding Your Treatment Possibilities

- ✔ Multiple offset lumens provide dose shaping opportunities to minimize skin and rib dose
- ✔ Vacuum ports enable the removal of fluid & air and facilitate tissue conformance to the balloon for more uniform dosing
- ✔ Polyurethane balloon maintains symmetry and reduces potential for balloon rupture

SenoRx

About SenoRx

Investor Relations
Press Releases
Quality Policy

SenoRx was founded in 1998 to design, develop, manufacture and market minimally invasive devices for the diagnosis and treatment of breast cancer. Since its founding, SenoRx has developed multiple, proprietary technology platforms and a unique product portfolio that address the entire range of diagnostic and therapeutic procedures. It is the goal of SenoRx to become the leader in the marketplace by offering products and procedures that dramatically enhance patient outcomes.

SenoRx (NASDAQ: SENO), which completed its initial public offering of common stock in March 2007, develops, manufactures and sells minimally invasive medical devices used by breast care specialists for the diagnosis of breast cancer. SenoRx's field sales organization serves over 1,000 breast diagnostic and treatment centers in the United States and Canada. With 17 products that have already received FDA 510(k) clearance across the continuum of breast care, SenoRx is developing additional minimally invasive products for diagnosis and treatment of breast cancer.

SenoRx has a strong portfolio of intellectual property. The company currently has 43 issued United States patents primarily covering devices relating to breast biopsy, including biopsy site marking devices, excision devices, and balloon products, and a total

of 13 granted national patents from eight different European countries. In addition, SenoRx has 66 pending United States patent applications and 19 pending European patent applications.

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Press Release

SENORX LAUNCHES CONTURA™ MLB

ALISO VIEJO, California, January 17, 2008 – SenoRx, Inc. (NASDAQ:SENO) today announced that it has launched Contura™, its Multi-Lumen Balloon (MLB) Catheter for delivering brachytherapy to the surgical margins following lumpectomy for breast cancer. The company had previously said that it intended to transition from user preference testing, which had expanded to 34 clinical sites by the end of 2007, to full commercial launch in January 2008.

Contura is one of a new class of devices which is designed to reduce radiation treatment time to five days from six to eight weeks in patients eligible for the treatment. SenoRx believes that the Contura MLB can play an important role in the shift from traditional whole breast radiation therapy to localized partial breast radiation therapy. Some patients who are presently candidates for balloon therapy are currently excluded because of the location of the lesion and their breast size. Contura's advanced multi-lumen design may address this issue for certain patients. In addition, the Contura MLB uses vacuum suction to remove excess seroma and air to enhance conformance of often irregularly shaped lumpectomy cavity walls to the balloon surface in order to deliver precise radiation dosing through multiple radiation source lumens. SenoRx has been granted three patents related either to the design or manufacturing of Contura and has additional patents pending.

"Since the 510(k) clearance from the U.S. Food and Drug Administration on May 23, 2007, the positive feedback that we have gathered for Contura during the pre-launch evaluation conducted in the second half of the year, has strengthened our belief that its innovative multi-lumen design, along with the vacuum feature and its propriety manufacturing process, can provide the clinical advantages we had hoped to achieve," said Lloyd Malchow, SenoRx President and Chief Executive Officer. "We are further pleased that several clinical sites have already submitted papers and abstracts for presentation at upcoming oncology meetings."

SenoRx recently provided its initial estimate for 2008 revenues for all of its product lines, which is expected to be in a range of $46 million to $50 million.

About SenoRx

SenoRx (NASDAQ: SENO) develops, manufactures and sells minimally invasive medical devices used by breast care specialists for the diagnosis and treatment of breast cancer, including its flagship EnCor® system and Contura™ MLB. SenoRx's field sales organization serves over 1,000 breast diagnostic and treatment centers in the United States and Canada. With 18 products having received FDA 510(k) clearance across the continuum of breast care, SenoRx is developing additional minimally invasive products for diagnosis and treatment of breast cancer. For more information, visit the company's website at www.senorx.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Specifically, statements concerning the expected clinical advantages of Contura™ MLB and the company's financial guidance are forward-looking statements within the meaning of the Safe Harbor. Forward-looking statements are based on management's current, preliminary expectations and are subject to risks and uncertainties, which may cause SenoRx's actual results to differ materially from the statements contained herein. Information on potential risk factors that could affect SenoRx's business and its financial results are detailed in its most recent quarterly report on Form 10-Q, as filed with the Securities and Exchange Commission. Undue reliance should not be placed on forward-looking statements, especially guidance on future financial performance, which speaks only as of the date they are made. SenoRx undertakes no obligation to update publicly any forward-looking statements to reflect new information, events or circumstances after the date they were made, or to reflect the occurrence of unanticipated events.

CONTACT: SenoRx, Inc.
Lila Churney, Director of Investor Relations
949-362-4800 x 132

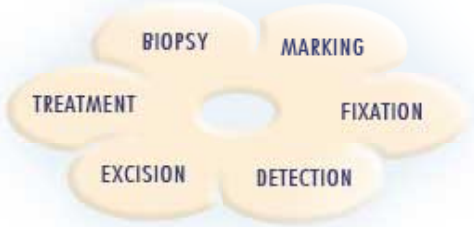
Treatment

Marker Comparisons

Procedure Video

Reimbursement Guidelines

Professional Education



For Patients: After lumpectomy procedure, your physician may recommend whole or partial breast radiation treatment to potentially reduce the recurrence of cancer cells in the lumpectomy site.

Contura™
Multi-Lumen Balloon • MLB

The current standard of care for treatment of breast cancer following lumpectomy is whole breast radiation. This requires the patient to return to the radiology suite daily for five to eight weeks.

SenoRx has developed Contura™, a multi-lumen radiation balloon applicator for accelerated partial breast irradiation. The radiation balloon uses vacuum to remove excess fluid and to adhere closely to often irregularly shaped lumpectomy cavities in order

to deliver precise radiation dosing through multiple seed lumens. Treatment time is reduced to days versus weeks, and accurate, targeted radiation dosing decreases potential recurrence of cancer cells in the lumpectomy site.

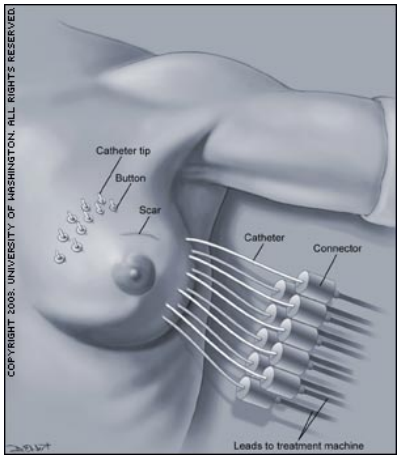
With our advanced multi-lumen design, more accurate treatment is achieved. Certain patients who are presently candidates for balloon therapy are currently excluded because of the location of the lesion relative to their breast size. Our multi-lumen approach offers a solution to this problem.

UW Medical Center

UNIVERSITY OF WASHINGTON MEDICAL CENTER
UW Medicine

1959 NE Pacific / Seattle, WA / 206-598-3300

Interstitial Breast Brachytherapy Patient Information



Preparation for Treatment

The initial catheter placement for this treatment is performed at the Seattle Cancer Care Alliance. You will need to bring your medications with you to take as instructed by your nurse.

Transportation

Make sure you have arranged transportation home after your procedure. You will not be able to drive yourself because of the sedating effects of the medications. Your nurse will have more specific information on these medications during your radiation oncology visit.

Diet

You can eat a light breakfast or lunch one hour prior to arrival, but you may want to limit fluid intake until after the procedure.

What to wear

Loose fitting clothing that buttons down the front will make it easier to get dressed after your procedure.

Aspirin or anticoagulants

Do not take aspirin or anticoagulation medications prior to your procedure. Discuss this with your doctor.

Herbal supplements

Stop herbal supplements one to two weeks prior to procedure.

Thermometer

You will need an oral thermometer to check your temperature three times a day.

Placement of the Treatment Catheters

When your procedure starts, your breast will be numb from the Emla cream. First, an ultrasound will be performed to identify the lumpectomy cavity. Fluid will be drawn from the cavity with a syringe and a contrast dye will be injected. Tell the nurse or doctor if you have had any previous reactions to contrast dye. Constrast dye helps your doctor see the area of needle placement more accurately under mammography.

Next, you will be taken to the mammography room for placement of the brachytherapy catheters. Your breast will be scrubbed with an antibacterial solution to help prevent infection. Then you will be positioned face down on the table, with your affected breast lying through a hole in the table. The medication you took should help you feel relaxed and as comfortable as possible while in this position for the procedure. A plastic template is then applied to the

breast. The template has many little holes that help your doctor to guide the needles in the correct location around the lumpectomy cavity. A mammogram is taken with the template in place to ensure that it is in the right location for placement of the catheters. Once the doctor is sure that the template is in the right location, a mixture of medications will be injected into the breast that will numb the skin and tissue before placement of the needles.

After the breast is thoroughly numb, the needles are placed. Another film is taken to be sure that the needles are all in the correct location. Then the plastic catheters are threaded through the needles and the needles are removed.

You will be assisted to a sitting position, and little plastic buttons will be applied to the ends of the catheters to secure them in place. Your nurse will apply antibiotic ointment to the skin at the catheter entrance and exit sites. This will help to prevent infection. A surgical bra and additional sterile dressings will help keep everything clean and the catheters in place.

Finally, you will be allowed to be driven home. You should take your pain medications as told. You will return the next day to the UW Medical Center Cancer Center for filming and a dressing change.

Daily Treatments

On the following Monday, your radiation treatments will begin. You will be treated twice a day, with about six hours between treatments. When you arrive, a receptionist will page your nurse who will escort you to the brachytherapy treatment room and help

you to get comfortable on a stretcher. The nurse will remove your surgical bra and dressings and check your skin for any infection or irritation. Your doctor and a physicist will connect the numbered catheters to a flexible cable. Each cable will then be connected to the treatment machine. Your treatment will be delivered and monitored from outside the room.

During the treatment, a radioactive seed will slide inside each catheter and stay there for the proper amount of time. You will not feel the radiation treatment as it is given. You will hear a clicking sound from the treatment machine.

Your nurse will then apply new dressings and you will be allowed to leave the clinic until your next scheduled appointment. There will be no radiation left inside your body after the treatment. You should expect the entire process to take about one hour each time.

After Treatment

After your last treatment, the catheters are removed with very little discomfort. There is usually little or no bleeding. Your nurse will cleanse the breast and apply antibiotic ointment to the catheter entry and exit sites.

Your nurse will send you home with all the skin care supplies you will need to care for yourself after treatment. The nurse will review instructions for your care at home and when to call your nurse or doctor.

You will need to keep checking your temperature twice a day. Call us if your temperature exceeds 100.5 degrees F, or if you notice

increased redness, tenderness, or cloudy drainage from any holes.

You will follow up one month after treatment. If you come from out of state, your local doctor can monitor you for the first six months. You should return to the UW Medical Center Cancer Center six months after brachytherapy for your first post-treatment mammogram and physical examination.

Page Last Modified On 4/3/2004

How It Works

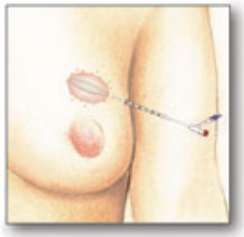
View a demonstration of this procedure.

Joan shares her story.

Click here

MammoSite 5-Day Targeted Radiation Therapy simplifies breast cancer treatment...

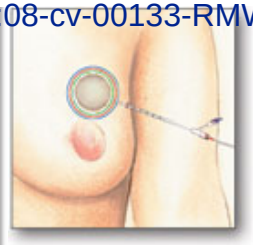
1. Placement



After the breast cancer tumor is removed (lumpectomy), a small, soft MammoSite balloon attached to a thin tube (catheter) is placed inside the lumpectomy cavity through a small incision in the breast.

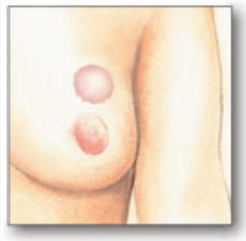
- The balloon is "inflated" with saline solution so that it fits snugly into the cavity. It remains inflated during the 5-day treatment.
- A small portion of the catheter remains outside the breast; this is secured to a cushioned gauze pad to prevent movement of the catheter.

2. Treatment



- Treatment is planned by a radiation oncologist who will take images of the MammoSite balloon catheter in the breast and determine the amount of radiation needed.
- During therapy, the portion of the catheter that remains outside your breast is connected to a computer-controlled High Dose Rate (HDR) machine that inserts a radiation "seed" to deliver the therapy.
- Once therapy is complete, the seed is removed, the catheter is unplugged, and you will be free to return to your normal daily activities.
- No radiation remains inside your breast in between treatments.

3. Removal



- After 5 days of treatment, your MammoSite balloon catheter will be removed, usually on the last day of treatment.
- The balloon is gently removed through the same incision made to place it.

Delaine, Ft. Lauderdale, FL

"It's fast. It doesn't hurt."

Click here to see Delaine's Story.

To hear more stories, visit www.VoicesofMammoSite.com

Maryanna, San Antonio, TX

"I am soon to be a five-year survivor thanks to MammoSite!"

Click here to see Maryanna's Story.

To hear more stories, visit www.VoicesofMammoSite.com

SenoRx Reports Third Quarter 2007 Results

Continued Strong Growth in Revenue and Gross Margin

ALISO VIEJO, Calif., Nov 13, 2007 (PrimeNewswire via COMTEX News Network) -- SenoRx, Inc. (Nasdaq:SENO) today reported financial results for its third quarter ended September 30, 2007. Revenue for the quarter increased 44.9 percent to $8.9 million, compared with $6.1 million in the third quarter of 2006. Gross profit increased 88.0 percent to $5.4 million, or 60.1 percent of revenue, up from $2.8 million, or 46.3 percent of revenue, in the third quarter of 2006.

SenoRx reported an operating loss for the third quarter of $1.8 million, an improvement of 28.8 percent compared with $2.5 million in the same period last year. The operating loss for the quarter included additional administrative expenses of approximately $338,000 incurred during the period associated with being a public company and stock-based compensation expense of $655,000, compared with $289,000 in the third quarter of 2006.

Net loss for the third quarter of 2007 declined 37.2 percent to $1.7 million or 10 cents per share, compared with $2.7 million or $1.15 per share for the third quarter of 2006. Contributing to the reduction in net loss for the third quarter was a significant swing to net interest income from net interest expense resulting from the IPO proceeds.

"We are pleased to report another strong quarter for SenoRx. Revenues continued to grow strongly, led by a 44.9 percent increase in biopsy disposable revenues over the same period year ago. Also contributing to the revenue increase were new incremental commercial sales of our new Contura(tm) Multi-Lumen Balloon (MLB), as well as a significant increase in biopsy capital revenue for the third quarter," said Lloyd Malchow, SenoRx President and Chief Executive Officer. "We also continued to expand our gross margin, which showed significant improvement over the third quarter last year, and continued the positive sequential trend we have been achieving during 2007. Continued growth in the installed base of EnCor systems, favorable product sales mix, improved leverage of our manufacturing overhead across increased sales volume, and continued cost reduction as we transition certain component manufacturing to low-cost FDA-approved suppliers all contributed to the improvement in gross margin."

For the first nine months of 2007, SenoRx revenues increased 35.1 percent to $24.7 million, compared with $18.3 million for the same period in 2006. Gross profit grew 59.5 percent to $14.1 million from $8.9 million in the first nine months of last year. Net loss for the first nine months of 2007 decreased to $5.9 million compared with $11.5 million for the same period a year ago.

2007 Outlook

SenoRx is encouraged by the continued positive progress towards its financial performance objectives over the first nine months of 2007, and remains focused on executing its strategic plan. With the company's current product offering, including regulatory approval of the Contura MLB and most recently SenoSonix(tm), an integrated breast biopsy system with state-of-the-art ultrasound imaging, the company believes it is well positioned to become a leader in both the diagnostic and therapeutic breast care market. Based on the current outlook, SenoRx management has narrowed its guidance for full-year 2007 revenues to $34 to $35 million.

In addition, SenoRx has determined to use a portion of its IPO cash proceeds to retire the 2006 subordinated note prior to year end. The subordinated note bears an interest rate of 11.5 percent per annum and does not carry a prepayment penalty. Retirement of the subordinated note will result in an approximate use of cash in the amount of $10.4 million representing the principal balance and accrued unpaid interest. The company estimates the retirement of the subordinated note will result in a non-cash charge to non-operating expense of approximately $1.3 million in the fourth quarter of 2007, representing the unamortized debt issuance and debt discount costs which would have otherwise been charged to interest expense over the term of the subordinated note. The company intends to continue maintaining a credit facility on a going forward basis.

2008 Outlook

SenoRx management is currently conducting its annual strategic plan and expects to provide revenue guidance for 2008 by calendar year end 2007, following approval by management and the Board of Directors.

Conference Call

SenoRx will host a conference call at 2:00 p.m. Pacific Standard Time on Tuesday, November 13. The conference call can be accessed by calling (888)230-6285 or via the company's website www.senorx.com.

About SenoRx

SenoRx (Nasdaq:SENO), which completed its initial public offering of common stock in April 2007, develops, manufactures and sells minimally invasive medical devices used by breast care specialists for the diagnosis of breast cancer. SenoRx's field sales organization serves over 1,000 breast diagnostic and treatment centers in the United States and Canada. With 18 products that have already received FDA 510(k) clearance across the continuum of breast care, SenoRx is developing additional minimally invasive products for diagnosis and treatment of breast cancer. For more information, visit the company's website at www.senorx.com.

The SenoRx, Inc. logo is available at http://www.primenewswire.com/newsroom/prs/?pkgid=3605

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Specifically, statements concerning SenoRx's financial guidance for fiscal year 2007 are forward-looking statements within the meaning of the Safe Harbor. Forward-looking statements are based on management's current, preliminary expectations and are subject to risks and uncertainties, which may cause SenoRx's actual results to differ materially from the statements contained herein. SenoRx's third quarter September 30, 2007 financial results, as discussed in this release, are preliminary and unaudited, and subject to adjustment. Further information on potential risk factors that could affect SenoRx's business and its financial results are detailed in its prospectus dated March 29, 2007 and its most recent quarterly report on Form 10-Q, in each case as filed with the Securities and Exchange Commission. Undue reliance should not be placed on forward-looking statements, especially guidance on future financial performance, which speaks only as of the date they are made. SenoRx undertakes no obligation to update publicly any forward-looking statements to reflect new information, events or circumstances after the date they were made, or to reflect the occurrence of unanticipated events.

SENORX, INC.
CONDENSED BALANCE SHEETS
(Unaudited)

	September 30, 2007	December 31, 2006
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 29,136,338	$ 7,412,986
Short-term investments	13,068,123	--
Accounts receivable, net of allowance for doubtful accounts of $113,169 and $120,000, respectively	5,338,554	4,241,307
Inventory	5,920,860	4,988,695
Prepaid expenses and deposits	691,797	220,659
Total current assets	54,155,672	16,863,647
Property and equipment, net	1,066,060	1,100,599
Other assets, net of accumulated depreciation of $442,956, and $539,602, respectively	539,899	2,017,079
TOTAL	$ 55,761,631	$ 19,981,325
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		

Current Liabilities:		
Accounts payable	$ 1,622,402	$ 4,122,477
Accrued expenses, including accrued employee compensation of $786,914 and $507,829, respectively	2,801,971	2,109,226
Deferred revenue--current	66,850	36,050
Current portion of long-term debt	4,883,797	3,209,621
Total current liabilities	9,375,020	9,477,374
Long-term debt--less current portion	8,837,553	10,596,147
Warrant liability	--	1,529,250
Total long-term liabilities	8,837,553	12,125,397
Convertible promissory notes (at fair value)	--	11,960,000
Commitments and contingencies (Note 12)		
Stockholders' Equity (Deficit):		
Series A convertible preferred stock -- $1.00 par value; 3,000,000 shares authorized,issued and outstanding (2006) (aggregate liquidation value of $3,000,000)	--	3,000,000
Series B convertible preferred stock -- $2.50 par value; 3,532,040 shares authorized; 3,523,040 issued and outstanding (2006) (aggregate liquidation value of $8,807,600)	--	8,807,600
Series C convertible preferred stock -- $1.96 par value; 19,500,000 shares authorized; 17,861,899 (2006) issued and outstanding (aggregate liquidation value of $35,009,323)	--	35,009,323
Common stock, $0.001 par value -- 100,000,000 shares authorized; 17,107,635 (2007) and 2,371,002 (2006) issued and outstanding	17,108	2,371
Additional paid-in capital	109,006,086	5,262,394
Deferred compensation	(2,662)	(126,658)
Accumulated deficit	(71,471,474)	(65,536,476)
Total stockholders' equity (deficit)	37,549,058	(13,581,446)
TOTAL	$ 55,761,631	$ 19,981,325

SENORX, INC.
CONDENSED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Net revenues	$8,906,086	$6,147,677	$24,727,447	$18,309,700
Cost of goods sold	3,555,638	3,301,367	10,582,993	9,441,656
Gross profit	5,350,448	2,846,310	14,144,454	8,868,044
Operating expenses:				

Selling and marketing	4,354,056	3,588,887	13,085,547	10,688,447
Research and development	1,580,130	1,423,762	4,694,999	3,866,133
General and administrative	1,205,515	345,777	3,092,703	1,504,932
Total operating expenses	7,139,701	5,358,426	20,873,249	16,059,512
Loss from operations	(1,789,253)	(2,512,116)	(6,728,795)	(7,191,468)
Interest expense	452,670	231,017	1,379,405	612,256
Change in fair value of convertible promissory notes and warrant valuation	--	--	(990,875)	3,820,000
Interest Income	(551,288)	(55,262)	(1,182,327)	(115,970)
Loss before provision for income taxes	(1,690,635)	(2,687,871)	(5,934,998)	(11,507,754)
Provision for income taxes	--	3,000	--	8,000
Net loss	$(1,690,635)	$(2,690,871)	$(5,934,998)	$(11,515,754)
Net loss per share - basic and diluted	$(0.10)	$(1.15)	$(0.50)	$(4.98)
Weighted average shares outstanding - basic and diluted	17,076,002	2,331,054	11,973,240	2,313,663

REVENUE BY PRODUCT CLASS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Biopsy disposable products	$3,945,941	$2,723,793	$11,487,122	$7,667,470
Biopsy capital equipment products	1,029,065	294,494	2,130,294	1,019,958
Diagnostic adjunct products	3,744,039	3,129,390	10,897,893	9,622,272
Therapeutic disposables	187,041	--	212,138	--
Total	$8,906,086	$6,147,677	$24,727,447	$18,309,700

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SOURCE: SenoRx, Inc.

SenoRx, Inc.
Lila Churney, Director of Investor Relations
949.362.4800 ext.132

News Provided by COMTEX

Press Release

SENORX PROVIDES INITIAL ESTIMATE FOR 2008 REVENUE

ALISO VIEJO, California, December 20, 2007 – SenoRx, Inc. (NASDAQ:SENO) today provided its initial estimate for revenues in 2008, which it expects will be in a range of $46 million to $50 million. SenoRx had previously indicated that it would be finalizing its annual strategic plan in December and would provide its estimate for 2008 revenues at that time.

"We are encouraged by the continuing progress we have achieved during 2007 and feel positive about the fundamentals of our business, including the increasing pace of placements for our EnCor® breast biopsy system," said Lloyd Malchow, SenoRx President and Chief Executive Officer. "We believe that key elements of our growth will be our Contura™ MLB radiation balloon, which we expect to transition from preference testing, currently expanded to 34 clinical sites, to full commercial launch in January 2008, as well as continued favorable reimbursement patterns.

"In addition, to further assist investors in developing achievable earnings models for our financial performance in 2008, we are providing an initial estimate for deferred compensation and equity-based compensation expense, which we currently expect will range between $2.8 million and $3.2 million for the coming year," continued Malchow. "These ranges could be materially impacted based upon fluctuation in the market price of the company's common stock. We will continue to provide separate disclosure on a quarterly basis related to this item of expense. Deferred compensation and equity-based compensation charges in our recently reported third quarter were $655,000."

About SenoRx

SenoRx (NASDAQ: SENO) develops, manufactures and sells minimally invasive medical devices used by breast care specialists for the diagnosis and treatment of breast cancer, including its flagship EnCor® system and Contura™ MLB. SenoRx's field sales organization serves over 1,000 breast diagnostic and treatment centers in the United States and Canada. With 18 products having received FDA 510(k) clearance across the continuum of breast care, SenoRx is developing additional minimally invasive products for diagnosis and treatment of breast cancer. For more information, visit the company's website at www.senorx.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Specifically, statements concerning the expectations of future revenue growth, the timing of our Contura commercial launch, the company's ability to maintain its product pricing, the company's financial guidance, and the factors that would impact that guidance, are forward-looking statements within the meaning of the Safe Harbor. Forward-looking statements are based on management's current, preliminary expectations and are subject to risks and uncertainties, which may cause SenoRx's actual results to differ materially from the statements contained herein. Information on potential risk factors that could affect SenoRx's business and its financial results are detailed in its most recent quarterly report on Form 10-Q, as filed with the Securities and Exchange Commission. Undue reliance should not be placed on forward-looking statements, especially guidance on future financial performance, which speaks only as of the date they are made. SenoRx undertakes no obligation to update publicly any forward-looking statements to reflect new information, events or circumstances after the date they were made, or to reflect the occurrence of unanticipated events.

CONTACT: SenoRx, Inc.
Lila Churney, Director of Investor Relations
949-362-4800 x 132

Table C-10.
U.S. District Courts—Median Time Intervals from Filing to Trial of Civil Cases in Which Trials Were Completed, by District, During the 12-Month Period Ending September 30, 2006

Circuit and District	Total Trials		Nonjury Trials		Jury Trials	
	Number of Trials	Median Time Interval in Months*	Number of Trials	Median Time Interval in Months*	Number of Trials	Median Time Interval In Months*
TOTAL	**3,201**	**23.2**	**1,107**	**21.0**	**2,094**	**24.8**
DC	**29**	**37.0**	**9**	**-**	**20**	**34.0**
1ST	**154**	**26.7**	**55**	**26.0**	**99**	**26.0**
ME	14	17.0	6	-	8	-
MA	80	28.0	29	28.5	51	27.0
NH	7	-	-	-	7	-
RI	19	19.0	8	-	11	15.0
PR	34	33.0	12	28.0	22	34.0
2ND	**320**	**29.9**	**108**	**25.0**	**212**	**31.8**
CT	52	29.8	13	26.0	39	29.0
NY,N	33	42.0	6	-	27	42.0
NY,E	62	29.0	19	30.5	43	29.0
NY,S	143	25.7	67	23.4	76	26.4
NY,W	21	41.8	3	-	18	41.9
VT	9	-	-	-	9	-
3RD	**308**	**24.3**	**104**	**22.4**	**204**	**26.0**
DE	26	26.0	12	24.0	14	26.0
NJ	61	33.0	29	30.5	32	34.0
PA,E	117	18.0	39	19.0	78	18.4
PA,M	47	20.0	12	9.0	35	20.9
PA,W	52	33.5	10	19.0	42	34.5
VI	5	-	2	-	3	-
4TH	**238**	**19.5**	**90**	**17.0**	**148**	**20.6**
MD	33	25.0	9	-	24	21.0
NC,E	28	22.0	22	18.0	6	-
NC,M	8	-	5	-	3	-
NC,W	5	-	1	-	4	-
SC	67	21.8	18	27.0	49	20.8
VA,E	48	9.3	27	8.5	21	10.0
VA,W	29	18.4	5	-	24	16.0
WV,N	5	-	-	-	5	-
WV,S	15	20.0	3	-	12	19.0

Table C-10. (September 30, 2006—Continued)

Circuit and District	Total Trials		Nonjury Trials		Jury Trials	
	Number of Trials	Median Time Interval in Months*	Number of Trials	Median Time Interval in Months*	Number of Trials	Median Time Interval In Months*
5TH	**471**	**21.1**	**188**	**19.7**	**283**	**22.8**
LA,E	64	20.0	36	22.0	28	19.2
LA,M	6	-	1	-	5	-
LA,W	36	25.5	19	25.0	17	25.0
MS,N	37	24.0	4	-	33	24.0
MS,S	63	25.5	26	25.0	37	24.0
TX,N	59	20.0	22	17.0	37	23.0
TX,E	50	17.7	8	-	42	17.0
TX,S	106	18.8	51	13.0	55	22.0
TX,W	50	14.6	21	11.0	29	19.8
6TH	**256**	**25.9**	**54**	**23.5**	**202**	**25.6**
KY,E	9	-	1	-	8	-
KY,W	16	27.5	1	-	15	27.5
MI,E	66	24.0	12	15.0	54	25.8
MI,W	11	36.0	3	-	8	-
OH,N	39	22.3	9	-	30	22.8
OH,S	26	27.0	9	-	17	30.4
TN,E	31	26.5	8	-	23	23.0
TN,M	28	25.4	6	-	22	26.0
TN,W	30	24.7	5	-	25	24.0
7TH	**217**	**24.4**	**58**	**24.0**	**159**	**25.7**
IL,N	91	26.4	32	26.0	59	26.5
IL,C	23	30.0	4	-	19	30.5
IL,S	24	20.0	6	-	18	19.0
IN,N	10	25.0	-	-	10	25.0
IN,S	33	26.0	11	23.0	22	26.0
WI,E	11	28.0	1	-	10	28.0
WI,W	25	13.4	4	-	21	13.4
8TH	**244**	**21.4**	**76**	**21.3**	**168**	**21.5**
AR,E	72	21.7	27	21.0	45	21.0
AR,W	27	13.0	7	-	20	13.5
IA,N	10	17.0	3	-	7	-
IA,S	12	24.0	4	-	8	-
MN	26	26.4	5	-	21	27.0
MO,E	31	21.5	8	-	23	19.0
MO,W	24	23.4	6	-	18	23.0
NE	26	21.0	12	22.0	14	20.0
ND	9	-	3	-	6	-
SD	7	-	1	-	6	-

Table C-10. (September 30, 2006—Continued)

Circuit and District	Total Trials		Nonjury Trials		Jury Trials	
	Number of Trials	Median Time Interval in Months*	Number of Trials	Median Time Interval in Months*	Number of Trials	Median Time Interval In Months*
9TH	**462**	**26.0**	**199**	**22.2**	**263**	**28.9**
AK	1	-	-	-	1	-
AZ	57	32.0	24	31.0	33	33.0
CA,N	56	25.0	25	26.0	31	25.0
CA,E	41	34.0	9	-	32	36.0
CA,C	134	21.3	70	16.9	64	25.0
CA,S	31	33.0	11	30.0	20	33.0
HI	12	10.0	9	-	3	-
ID	10	30.0	6	-	4	-
MT	6	-	4	-	2	-
NV	32	29.5	17	25.5	15	30.0
OR	30	27.0	7	-	23	32.5
WA,E	15	17.0	4	-	11	17.0
WA,W	34	19.0	13	21.0	21	18.3
GUAM	1	-	-	-	1	-
NMI	2	-	-	-	2	-
10TH	**175**	**22.5**	**51**	**21.0**	**124**	**22.0**
CO	53	32.0	15	32.0	38	29.0
KS	22	21.0	6	-	16	22.0
NM	21	15.8	8	-	13	16.5
OK,N	13	19.0	1	-	12	18.0
OK,E	5	-	2	-	3	-
OK,W	29	16.4	5	-	24	16.7
UT	24	25.0	13	30.0	11	23.0
WY	8	-	1	-	7	-
11TH	**327**	**21.9**	**115**	**18.2**	**212**	**23.2**
AL,N	39	28.5	7	-	32	28.0
AL,M	14	20.0	3	-	11	20.0
AL,S	7	-	2	-	5	-
FL,N	19	19.0	7	-	12	17.0
FL,M	74	19.2	28	18.5	46	22.0
FL,S	98	16.3	43	14.8	55	19.7
GA,N	49	31.0	18	27.0	31	31.5
GA,M	17	23.0	5	-	12	28.0
GA,S	10	44.0	2	-	8	-

NOTE: INCLUDES TRIALS CONDUCTED BY DISTRICT AND APPELLATE JUDGES ONLY. ALL TRIALS CONDUCTED BY MAGISTRATE JUDGES ARE EXCLUDED. EXCLUDES THE FOLLOWING TRIALS: LAND CONDEMNATION; FORFEITURES AND PENALTY CASES; PRISONER PETITIONS (HABEAS CORPUS, MOTIONS TO VACATE SENTENCE UNDER 28 U.S.C. 2255, HEARINGS ON EVIDENTIARY MATTERS); BANKRUPTCY PETITIONS; AND THREE-JUDGE COURT CASES. FOR CIVIL CASES RESULTING IN A COMPLETED TRIAL, THE MEDIAN TIME IS BASED ON THE ORIGINAL FILING DATE AND THE DATE THE TRIAL WAS COMPLETED. FOR REOPENED CIVIL CASES RESULTING IN A SECOND COMPLETED TRIAL, THE MEDIAN TIME REMAINS BASED ON THE ORIGINAL FILING DATE AND THE DATE THE TRIAL WAS COMPLETED.

* TIME INTERVALS COMPUTED ONLY FOR 10 OR MORE TRIALS.

E-FILED on 4/27/07

IN THE UNITED STATES DISTRICT COURT

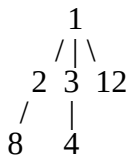
FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

XOFT, INC., Plaintiff, v. CYTYC CORPORATION; and PROXIMA THERAPEUTICS, INC., Defendants.	No. C-05-05312 RMW CLAIM CONSTRUCTION ORDER **[Re Docket Nos. 48, 50, 53]**

Xoft, Inc. sued Cytyc Corporation and one of its subsidiaries, Cytyc Surgical Products II, Inc., (collectively "Cytyc") for a declaratory judgment of non-infringement and invalidity of U.S. Patent Nos. 5,913,813 and 6,413,204. Cytyc responded by filing counterclaims for infringement of the same patents and currently asserts that Xoft infringes six claims of the '813 patent[1] and twenty

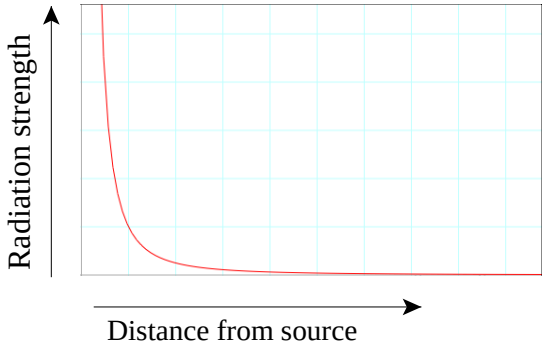
[1] Cytyc asserts claims 1, 2, 3, 4, 8, and 12. Claim 1 is an apparatus claim and the only independent claim of the '813 patent. Claims 2, 3, and 12 depend directly from claim 1. Claim 4 depends from claim 3, and claim 8 depends from claim 2. The following is a graphic representation of the relationship of the asserted claims:



claims of the '204 patent[2]. The application for the '204 patent was filed as a continuation-in-part of the '813 patent; the former purports to incorporate by reference the latter. '204 patent, col. 1, ll. 10-11. The parties seek construction of eight terms or phrases from the '813 patent and twenty-one terms or phrases from the '204 patent.

I. BACKGROUND

The patents-in-suit are directed to methods and apparatus for treatment of proliferative tissue diseases. The prior art discloses that a radiation source can be implanted at a tumor site to irradiate any remaining diseased tissue; this process is known as interstitial brachytherapy. The parties agree that for the purposes of this suit, the strength of radiation may be assumed to decrease with the square of the distance from the radiation source. The graph of the equation $y = 1 / x^2$ thus can be used as an approximation of the relationship between the radiation strength and distance. The graph, shown below, illustrates that the radiation strength close to the radiation source is disproportionately higher than that at a relatively small distance away from the radiation source.

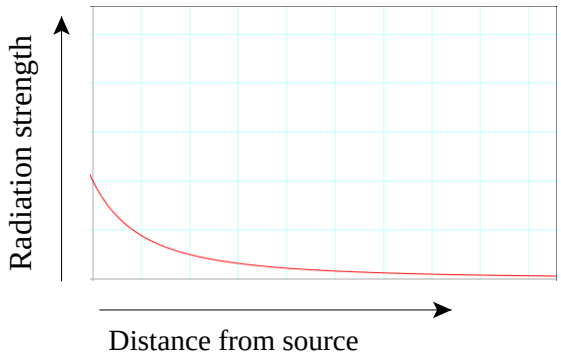


[2] Cytyc asserts claims 1, 2, 3, 4, 8, 16, 17, 18, 19, 20, 21, 23, 24, 25, 26, 30, 32, 34, 35, and 36 of the '204 patent. Claims 1 and 36 are the only independent apparatus claims. From claim 1 depend claims 2, 16, and 17. From claim 2 depend claims 4, 8, and 18. Claims 19, 32, and 34 are independent method claims. Claims 20, 21, 23, and 24 all depend from claim 19. Claim 25 depends from claim 24, and claim 26 depends from claim 25. Claim 30 also depends from claim 24. Claim 35 depends from claim 34. The following is a graphic representation of the relationship of the asserted claims:

```
      1          36          19          32          34
    / | \                  / / \ \                  |
  2  16  17           20 21 23 24                 35
 / | \                       /  \
4  8  18                   25   30
                           /
                          26
```

This shows one of the problems encountered in radiation therapy, namely, that tissue close to the radiation source may get more radiation than a physician would prefer. When using interstitial therapy, a physician may wish to give all tissue within a certain distance—say, for example, 3 centimeters—from the tumor site a certain dose of radiation. However, tissue closer to the tumor site—say, 1 centimeter—will receive a much higher dose of radiation because of the inverse-square relationship. This means that healthy tissue near the tumor site may be killed by the radiation, which is an undesirable result.

Following the teachings of the patents-in-suit, the very high levels of radiation near the source can be avoided by simple mechanical means. Surrounding the radiation source on all sides with empty space (or some material other than living tissue) prevents the highest levels of radiation from affecting living tissue, giving the tissue a radiation dose profile that looks something like this:



II. ANALYSIS

A. Terms of the '813 patent

"Inner spatial volume"

Cytyc's proposed construction	*Xoft's proposed construction*
A region of space surrounded by an outer spatial volume that is defined by a closed inflatable chamber	Inner balloon in two-balloon device or spherical solid radionuclide in one-balloon device

The summary of the invention provides that

> it is possible to deliver a desired radiation dose at a predetermined radial distance from a source of radioactivity by providing a first spacial[3] volume at the distal end of a catheter and a second spacial volume defined by a surrounding of the first spatial

[3] Presumably all occurrences of "spacial" in the '813 patent should be read as "spatial."

volume by a polymeric film wall where the distance from the spatial volume[4] and the wall is maintained substantially constant over their entire surfaces. One of the inner and outer volumes is filled with either a fluid or a solid containing a radionuclide(s) while the other of the two volumes is made to contain either a low radiation absorbing material, e.g., air or even a more absorptive material, such as an x-ray contrast fluid. Where the radioactive material comprises the core, the surrounding radiation absorbing material serves to control the radial profile of the radioactive emissions from the particular one of the inner and outer volumes containing the radionuclide(s) so as to provide a more radially uniform radiation dosage in a predetermined volume surrounding the outer chamber. Where the core contains the absorbent material, the radial depth of penetration of the radiation can be tailored by controlling the core size.

'813 patent, col. 1, l. 50-col. 2, l. 3. The first two claims of the '813 patent read:

1. Apparatus for delivering radioactive emissions to a body location with a uniform radiation profile, comprising:

(a) a catheter body member having a proximal end and distal end;

(b) an inner spatial volume disposed proximate the distal end of the catheter body member;

(c) an outer, closed, inflatable, chamber defined by a radiation transparent wall affixed to the body member proximate the distal end thereof in surrounding relation to the inner spatial volume with a predetermined constant spacing between said inner spatial volume and the radiation transparent wall;

(d) a material containing a radionuclide(s) disposed in one of the inner spatial volume and outer chamber; and

(e) means disposed in the other of the inner spatial volume and outer chamber for rendering uniform the radial absorbed dose profile of the emissions from the one of the inner spatial volume and outer chamber containing the radionuclides.

2. The apparatus as in claim 1 wherein said inner spatial volume is an inner closed, chamber defined by a further radiation transparent wall.

'813 patent, col. 4, ll. 32-54. Since all claims of this patent other than claim 1 depend from claim 1, construction of "inner spatial volume" is critical.

In most embodiments of the invention disclosed in the patent specification, the inner spatial volume is a region of space surrrounded by an outer spatial volume that is defined by a closed inflatable chamber. *See* '813 patent, col. 2, ll. 44-63; col. 3, ll. 9-16, 42-48; col. 4, ll. 16-20; figs. 1,

[4] Presumably this "spatial volume" should be taken to be the first spatial volume, which would mean that the polymeric film wall forms the outer boundary of the second spatial volume and that the second spatial volume is of a uniform thickness on all sides of the first spatial volume. Such a reading would comport with claim 1(c).

3-5. However, the patentee drafted the claims in such a way as to make clear that the inner spatial volume was not necessarily so limited:

> Those skilled in the art will appreciate that instead of having the inner spatial volume **30** defined by a generally spherical polymeric film wall as at **32**, the catheter body member **12** may have a solid spherical radiation emitting material in which event that solid sphere would be surrounded with the outer spherical wall **36** with the spatial volume therebetween occupied by a radioactive ray absorbent material, such as air, water or a contrast material.

'813 patent, col. 2, ll. 55-63.

Although somewhat awkwardly worded, the language of the patent allows for the inner volume to be defined by something other than a region enclosed by a polymeric wall. As Cytyc points out, Xoft's construction conflates the boundary of the volume with the volume itself. Cytyc's proposed construction, however, is a paraphrasing of the language of claim 1 that only clarifies a little the language of the patent. Furthermore, Cytyc's proposed construction would exclude an inner volume defined by a solid sphere, and thus cannot be correct.

Xoft objects that an abstract concept like a region of space cannot be part of an apparatus. Xoft is correct. However, the language of the patent does not imply that the inner volume is ever defined by something other than a physical object. In all embodiments of the invention disclosed in the '813 patent, the boundary of the inner volume is either a polymeric film wall or the edge of a solid sphere. Furthermore, it would seem difficult to fill one volume with radioactive liquid and the other with another fluid if the two volumes were not separated by some structure (which would necessarily be the outer boundary of the inner spatial volume.) *See* '813 patent, col. 1, ll. 57-62. The patent is even entitled "Double-Wall Balloon Catheter for Treatment of Proliferative Tissue." Xoft's expert, Dr. Lovoi, acknowledged that an "inner spatial volume" is a volume that is inside another volume. Lovoi Dep. at 101:25-102:7. The court defines "inner spatial volume" as "a region of space surrounded by an outer spatial volume and either enclosed by a polymeric film wall or defined by the edge of a solid radionuclide sphere."

Claim Language	***Court's Construction***
"inner spatial volume"	a region of space surrounded by an outer spatial volume and either enclosed by a polymeric film wall or defined by the outside surface of a solid radionuclide sphere

"Outer, closed, inflatable chamber"

Cytyc's proposed construction	*Xoft's proposed construction*
(no construction required)	Inflatable balloon, i.e., deflated balloon

Part (c) of claim 1 explains that the "outer, closed, inflatable chamber" is "defined by a radiation transparent wall affixed to the body member proximate the distal end thereof in surrounding relation to the inner spatial volume with a predetermined constant spacing between said inner spatial volume and the radiation transparent wall." '813 patent, col. 4, ll. 40-45. The preferred embodiment recites a similar structure: "Surrounding the spatial volume **30** is an outer chamber **34** defined by an outer polymeric film wall **36** that is appropriately spaced from the wall **32** of the inner chamber **30** when the two chambers are inflated or otherwise filled and supported." '813 patent, col. 2, ll. 37-41. There is no support in the patent for Xoft's argument that "outer, closed, inflatable chamber" should be limited to only a balloon in a deflated state. The court will therefore adopt Cytyc's proposal and not otherwise define this term.

Claim Language	***Court's Construction***
"outer, closed, inflatable chamber"	outer, closed, inflatable chamber

"Predetermined constant spacing"

Cytyc's proposed construction	*Xoft's proposed construction*
(no construction required)	(indefinite)

"Predetermined constant spacing between said inner spatial volume and radiation transparent wall"

Cytyc's proposed construction	*Xoft's proposed construction*
The spacing between the inner spatial volume and the radiation transparent wall of the outer, closed, inflatable chamber, when inflated, can be made constant in all directions if the outer chamber is spherical, or constant along a radial plane if the outer chamber is not spherical	(indefinite)

Xoft argues that the '813 patent is indefinite because it does not disclose how one "predetermines" the amount of spacing. Xoft points out that the spacing between the edges of the inner and outer volumes may change as parts of the apparatus are inflated or deflated, so the spacing is not constant. Cytyc's expert explained that "predetermined constant spacing" means that "the

spacing between the inner spatial volume and the wall of the outer inflatable chamber can be made constant in all directions if the outer chamber is spherical, or constant along a radial direction if non-spherical, whenever the outer chamber is inflated." Su Decl. (dkt. # 49), Ex. D (Verhey Decl.) at 7 (citations omitted). Cytyc also argues that "[o]ne skilled in the art knows how to determine an appropriate 'predetermined constant spacing' and Xoft provides no evidence, testimony, or case law to the contrary. Xoft cannot possibly show that the term is indefinite by clear and convincing evidence." Reply Br. (dkt. # 53) at 15.

Because 35 U.S.C. § 282 gives a patent "a statutory presumption of validity," a challenger bears the burden of proving "by clear and convincing evidence" that a patent is invalid. *Monsanto Co. v. Scruggs*, 459 F.3d 1328, 1336-37 (Fed. Cir. 2006). "[P]atent documents need not include subject matter that is known in the field of the invention." *S3 Inc. v. NVIDIA Corp.*, 259 F.3d 1364, 1371 (Fed. Cir. 2001). From the testimony of Dr. Verhey, it appears that one skilled in the art would know how to "predetermine" the amount of spacing.[5] *See* Tr. at 56-61, 85-89. Xoft offered no evidence suggesting otherwise. As the burden of proof is Xoft's, its indefiniteness argument necessarily fails given the absence of supporting evidence. The court will therefore adopt Cytyc's proposed construction of "predetermined constant spacing between said inner spatial volume and radiation transparent wall" modified only to make the definition easier to understand. A separate construction for "predetermined constant spacing" is not necessary.

Claim Language	***Court's Construction***
"predetermined constant spacing"	(no construction necessary)
"predetermined constant spacing between said inner spatial volume and radiation transparent wall"	spacing predetermined by one skilled in the art between the wall or edge of the inner spatial volume and the radiation transparent wall of the outer, closed, inflatable chamber, when inflated, which is constant in all directions if the outer chamber is spherical, or constant along a radial plane if the outer chamber is not spherical

[5] Xoft argues that the size of the cavity determines the size of the apparatus when fully inflated, but this alone does not determine the spacing between the inner spatial volume and the wall of the outer chamber.

"Rendering uniform"

Cytyc's proposed construction	*Xoft's proposed construction*
(no construction required)	Making the same, i.e., causing to have the same value or characteristic at all points.

"Means . . . for rendering uniform the radial absorbed dose profile of the emissions"

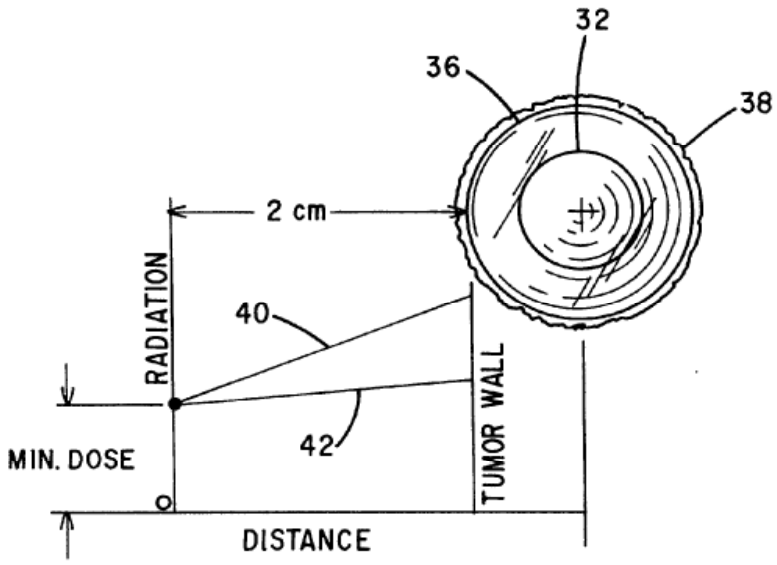
Cytyc's proposed construction	*Xoft's proposed construction*
Function: Modifying the ratio of the absorbed dose at a depth of interest in the target tissue to the absorbed dose at the surface of the tissue. Structure: A radiation absorbing or attenuating material, *e.g.*, air, x-ray contrast fluid, contrast media used in angiography, water, a gas, or barium sulfate.	Function: Making the dose along a radius extending from the radionuclide outwardly from the outer chamber wall the same at every point on the radius. Structure: No such means disclosed in '813 patent, means for making more uniform disclosed as substance within outer chamber.

Xoft's argument is that "uniform" must be taken literally, and the apparatus must produce radiation that does not decrease in strength with increasing distance from the source.[6] The parties do not dispute that Xoft's construction would require a physical impossibility; the strength of radiation necessarily decreases with distance from its source. Xoft, however, seeks to interpret "uniform" in a vacuum. The meaning of a particular word in a claim must be interpreted in light of the rest of the patent. *Ekchian v. Home Depot, Inc.*, 104 F.3d 1299, 1303 (Fed. Cir. 1997).

While the patent could have been drafted with more clarity, it is readily apparent that the patentee did not contemplate absolute uniformity. Figure 4 of the patent (reproduced below) is a comparison between the distance versus radiation dose plots of two scenarios. Line **40** shows the radiation dose that would result if chamber **36** were filled with a radioactive fluid. '813 patent, col. 3, ll. 20-24. Line **42** shows the radiation dose that would result if, following the teachings of the patent, the same radioactive fluid were contained only in chamber **32**. '813 patent, col. 3, ll. 24-28. As explained in the patent, "Comparing the plots **40** and **42**, by providing the concentric arrangement depicted, the absorbed dose profile in the space between the 2 cm site and the wall of the outer balloon is maintained much more uniform, thus preventing over-treatment of body tissue at

[6] Xoft also stated that it would "submit a Motion for Summary Judgment on this issue prior to the conduct of the *Markman* hearing," Responsive Br. (dkt. # 50) at 14, but did not do so.

or close to the outer wall **36** of the instrument." '813 patent, col. 3, ll. 28-33.



The patentee obviously did not expect absolute uniformity of radiation dosing. To interpret "uniform" in the manner urged by Xoft would go against the clear intent of the patentee. In *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443 (Fed. Cir. 1986), the defendant made a similar argument regarding the patentee's use of the term "smooth" with respect to the edges of contact lenses. The Federal Circuit looked to the intrinsic evidence and found that "smooth" did not mean absolutely ridge free but rather that it meant "smooth enough to serve the inventor's purposes, *i.e.*, not to inflame or irritate the eyelid of the wearer or be perceived by him at all when in place." *Id.* at 450. In this case, the inventor's purpose was to deliver radiation more uniformly than had previously been done, "thus preventing over-treatment of body tissue at or close to the outer wall . . . of the instrument." '813 patent, col. 3, ll. 28-32. The court will therefore define "rendering uniform" to mean to make the absorbed dose of radiation more uniform in order to prevent over-treatment of body tissue at or close to the outer wall of the instrument.

Since limitation language "means . . . for rendering uniform the radial absorbed dose profile of the emissions" is in means-plus-function format, the function must be construed and the corresponding structure or its equivalent identified in the specification. *BBA Nonwovens Simpsonville, Inc. v. Superior Nonwovens, L.C.C.*, 303 F.3d 1332, 1343 (Fed. Cir. 2002). As discussed, Xoft's definition of the function requires absolute uniformity which is not possible and which is not what the patent requires or the inventor intended. Cytyc's proposed definition construes the function as "modifying the ratio of the absorbed dose at a depth of interest in the target tissue to

the absorbed dose at the surface tissue." Although this appears to be a function of the invention, Cytyc's definition is too broad because it encompasses absorbed doses at the surface tissue that are not substantially uniform to absorbed doses at the target tissue. In other words, Cytyc's definition would not only encompass the radiation dose profile of line **42** above, but would also encompass the radiation doese profile of line 40. Furthermore, all radiation dose profiles between line 40 and line 42 that result in over-treatment of the surface tissue would also be included under Cytyc's definition. A more accurate construction of the function would require the absorbed dose at the target tissue and the absorbed dose at the surface tissue to be more uniform to prevent over-treatment of the surface tissue. Thus, the court defines the function of the "means . . . for rendering uniform the radial absorbed dose profile of the emissions" as making the absorbed dose of radiation more uniform to prevent over-treatment of body tissue at or close to the outer wall of the instrument.

Cytyc also identifies a radiation-absorbing or -attentuating material as the corresponding structure. At the claim construction hearing, Xoft argued that the uniformity of the radiation dose curve is solely affected by distance from the radiation source; the parties agree that this is true. *See* Tr. at 60-61. Although the composition of the material is not critical to the function, the radiation-absorbing or -attenuating material provides the distance necessary for achieving the uniformity in radiation dose curve. Thus, the court construes the language consistently with Cytyc's position.

Claim Language	***Court's Construction***
"rendering uniform"	to make the absorbed dose of radiation more uniform to prevent over-treatment of body tissue at or close to the outer wall of the instrument
"Means . . . for rendering uniform the radial absorbed dose profile of the emissions"	Function: Making the absorbed dose of radiation more uniform to prevent over-treatment of body tissue at or close to the outer wall of the instrument. Structure: A radiation absorbing or attenuating material, *e.g.*, air, x-ray contrast fluid, contrast media used in angiography, water, a gas, or barium sulfate or their equivalents.

"The radioactive material"

Cytyc's proposed construction	*Xoft's proposed construction*
The material of claim 1 containing a radionuclide.	(indefinite)

Claim 8 of the patent covers "[t]he apparatus as in claim 2 wherein the inner chamber contains the radioactive material." Claim 2 depends from claim 1. The parties dispute whether "a material containing a radionuclide(s)" suffices as an antecedent basis for "the radioactive material." It is readily apparent that the "radioactive material" in claim 8 refers back to "a material containing a radionuclide" described in claim 1, since "radionuclide" is the only radioactive material mentioned in claim 1. Anyone skilled in the art would so conclude. Xoft's contention that the term "radioactive material" is indefinite because it contains no antecedent basis is without merit. Xoft offers no authority suggesting that the antecedent basis of a term used in a dependent claim must be stated in identical words.[7] The court, therefore construes "the radioactive material" in claim 8 to be the "radionuclide(s)" referred to in claim 1.

Claim Language	***Court's Construction***
"The radioactive material"	The material of claim 1 containing a radionuclide.

"A plurality of radioactive solid particles placed at predetermined locations within the inner spatial volume to provide a desired composite radiation profile"

Cytyc's proposed construction	*Xoft's proposed construction*
A plurality of radioactive solid particles placed at pre-determined locations within the inner spatial volume to provide a desired dose profile that is the sum of the radiation profiles of the plurality of particles.	Static array of solid radioactive particles each placed in a single location and mounted on distal ends of separate wires. Desired composite radiation profile" is indefinite.

Claim 12 of the patent is directed to "[t]he apparatus as in claim 1 wherein the material containing a radionuclide comprises a plurality of radioactive solid particles placed at predetermined locations within the inner spatial volume to provide a desired composite radiation profile." Xoft argues claim 12 is indefinite on two grounds: first, that "desired composite radiation profile" is not

[7] At the *Markman* hearing, Xoft stated that it would provide a citation to such supporting authority. Tr. at 64. Xoft, however, has not done so.

defined, and second, that "inner spatial volume" is indefinite because no physical structure bounds it. The court rejects Xoft's second argument for the reasons given when construing "inner spatial volume" above. The court rejects Xoft's first argument because it presents no evidence that one skilled in the art would not understand "desired composite radiation profile."[8] Cytyc's proposed construction does not clarify the meaning of claim 12. However, since the language is understandable as is, no construction of "a plurality of radioactive solid particles placed at predetermined locations within the inner spatial volume to provide a desired composite radiation profile" is necessary or appropriate.

Claim Language	*Court's Construction*
"A plurality of radioactive solid particles placed at predetermined locations within the inner spatial volume to provide a desired composite radiation profile"	(no construction needed)

B. Terms of the '204 patent

Claim 1 of the '204 patent is similar to claim 1 of the '813 patent. Claim 1 of the '204 patent describes:

> An interstitial brachytherapy apparatus for delivering radioactive emissions to an internal body location comprising:
>
> (a) a catheter body member having a proximal end and distal end;
>
> (b) an inner spatial volume disposed proximate to the distal end of the catheter body member;
>
> (c) an outer spatial volume defined by an expandable surface element disposed proximate to the distal end of the body member in a surrounding relation to the inner spatial volume; and
>
> (d) a radiation source disposed in the inner spatial volume and generating a three-dimensional isodose profile that is substantially similar in shape to the expandable surface element.

[8] It would seem that for one skilled in the art, it would be a relatively simple matter to add up the individual radiation profiles of individual particles. *See* Tr. at 75-76.

"Interstitial"

Cytyc's proposed construction	*Xoft's proposed construction*
(no construction required)	Site in natural or surgically created cavity in body.

"Brachytherapy"

Cytyc's proposed construction	*Xoft's proposed construction*
Radiation therapy delivered by a spatially confined radiation source at or near the site of the diseased tissue.	Radiation therapy delivered by a spatially confined radionuclide at or near a tumor or other proliferative tissue disease site.

"Interstitial brachytherapy"

Cytyc's proposed construction	*Xoft's proposed construction*
Brachytherapy applied directly to the interspaces of a body tissue, where the interspaces are not naturally occurring.	Radiation therapy delivered by a spatially confined radionuclide at or near a tumor site in a natural or surgically created cavity in a body.

Cytyc argues that "interstitial" and "brachytherapy" should be constructed together; Xoft seeks a separate construction for each word. Cytyc also complains that Xoft seeks to limit "brachytherapy" to radionuclides, arguing that the definition should encompass any radiation source. However, the patent provides a clear definition of "brachytherapy": "The term 'brachytherapy,' as used herein, refers to radiation therapy delivered by a spatially confined radioactive material inserted into the body at or near a tumor or other proliferative tissue disease site." '204 patent, col. 1, ll. 30-33. Here, the patentee clearly acted as his own lexicographer, and Cytyc's arguments for a broader definition do not acknowledge this clear definition. The court construes "brachytherapy" to mean "radiation therapy delivered by a spatially-confined radioactive material inserted into the body at or near a tumor or other proliferative tissue disease site."[9]

Xoft argues that "interstitial" means any body cavity, while Cytyc argues that "interstitial" should be limited to only non-naturally-occurring cavities. As Xoft points out, one medical dictionary defines "interstitial" as "1. Placed or lying between. 2. Pert. to

[9] This definition does not resolve the parties' dispute over whether "radioactive material" should be read to encompass only "radionuclides" (as Xoft wishes) or any "radiation source" (as Cytyc urges). As the parties have separately sought construction of "radioactive material," the court will address construction of that phrase below.

interstices or spaces within an organ or tissue." TABER'S CYCLOPEDIC MEDICAL DICTIONARY, 1007 (Clayton M. Thomas, ed., 17th ed. 1993). Although not cited by the parties, a British oncology text indicates that "interstitial" has a particular meaning in the field of the invention:

> Two main techniques are used for the delivery of radiation which is given either as an external beam or as short range radiation from an implanted radioactive source. External beam radiation usually involves megavoltage produced by linear accelerator as photons or electrons or from cobalt sources in the form of relative low energy X-rays or gamma rays. The latter are often used to treat relatively superficial lesions such as basal cell carcinoma or recurrences within the skin. High energy radiation can be used to treat deeply located lesions such as prostatic carcinomas without delivering an excessive dose to adjacent normal tissue. . . .
>
> Interstitial implant irradiation gives a high local dose to the tumour and usually employes sources such as radium, iridium, or caesium used in the form of needles or wires implanted in the tumour. This technique is widely used in the treatment of head and neck cancers to deliver a high tumour dose without irradiation to sensitive organs such as the lens of the eye or the spinal cord.

I.S. Fentiman, *The local Treatment of Cancer*, INTRODUCTION TO THE CELLULAR & MOLECULAR BIOLOGY OF CANCER, 434, 446 (L.M. Franks & N.M. Teich, eds., 2d ed. 1991).

However, Cytyc points out that regardless of any generally-accepted meaning of "interstitial" in the field of the invention, the patentee limited "interstitial" during prosecution to refer to only surgically-created cavities (and similarly defined "intercavital" to refer to natural body cavities):

> Turning to the cited prior art, the Ishiwara device comprises a thermotherapeutic apparatus having a catheter body member, an inner lumen surrounded by an outer lumen, and a radiation source contained within the inner lumen. . . . Ishiwara's apparatus is inserted into a body cavity. Hence, the apparatus does not provide *interstitial* radiation treatment, as Applicant's invention requires, but rather intercavital radiation treatment.

Su Decl. (dkt. # 49), Ex. C (Amendment & Resp.) at 11 (citations omitted). This is consistent with the background section of the patent, which mentions surgical cavities several times but not natural ones. '204 patent, col. 1, ll. 19, 23, 25, 63, col. 2, l. 1. Also, although the summary section does not specify what type of cavities the apparatus claims are directed to, the summary makes clear that the method claims are directed to a method that "includes surgically creating access to the proliferating tissue within a patient and surgically resecting at least a portion of the proliferating tissue to create a resection cavity within body tissue." *Id.*, col. 3, ll. 3-6.

The parties did not brief the issue of how much weight the court should afford the prosecution history in this instance.[10] The Federal Circuit has instructed that "[a]lthough prosecution history can be a useful tool for interpreting claim terms, it cannot be used to limit the scope of a claim unless the applicant took a position before the PTO that would lead a competitor to believe that the applicant had disavowed coverage of the relevant subject matter." *Schwing GmbH v. Putzmeister Aktiengesellschaft*, 305 F.3d 1318, 1324 (Fed. Cir. 2002). Here, the patentee clearly disavowed coverage of intercavitary radiation treatment when arguing to the PTO. Given the

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[10] In its recent *en banc* explanation of the evidence to be used in construing claims, the Federal Circuit devoted a paragraph to prosecution history:

> In addition to consulting the specification, we have held that a court "should also consider the patent's prosecution history, if it is in evidence." *Markman*, 52 F.3d at 980; *see also Graham v. John Deere Co.*, 383 U.S. 1, 33, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966) ("[A]n invention is construed not only in the light of the claims, but also with reference to the file wrapper or prosecution history in the Patent Office."). The prosecution history, which we have designated as part of the "intrinsic evidence," consists of the complete record of the proceedings before the PTO and includes the prior art cited during the examination of the patent. *Autogiro*, 384 F.2d at 399. Like the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent. *See Lemelson v. Gen. Mills, Inc.*, 968 F.2d 1202, 1206 (Fed. Cir. 1992). Furthermore, like the specification, the prosecution history was created by the patentee in attempting to explain and obtain the patent. Yet because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes. *See Inverness Med. Switz. GmbH v. Warner Lambert Co.*, 309 F.3d 1373, 1380-82 (Fed. Cir. 2002) (the ambiguity of the prosecution history made it less relevant to claim construction); *Athletic Alternatives, Inc. v. Prince Mfg., Inc.*, 73 F.3d 1573, 1580 (Fed. Cir. 1996) (the ambiguity of the prosecution history made it "unhelpful as an interpretive resource" for claim construction). Nonetheless, the prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be. *Vitronics*, 90 F.3d at 1582-83; *see also Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1384 (Fed. Cir. 2005) ("The purpose of consulting the prosecution history in construing a claim is to 'exclude any interpretation that was disclaimed during prosecution.'"), quoting *ZMI Corp. v. Cardiac Resuscitator Corp.*, 844 F.2d 1576, 1580 (Fed. Cir. 1988); *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576 (Fed. Cir. 1995).

Phillips v. AWH Corp., 415 F.3d 1303, 1317 (Fed. Cir. 2005) (*en banc*).

intrinsic evidence is of primary importance[11] and all supports Cytyc's position, the court construes "interstitial" to mean "involving a surgically-created cavity in a body."

In light of the constructions of "interstitial" and "brachytherapy" above, no further construction of "interstitial brachytherapy" is necessary.

Claim Language	***Court's Construction***
"interstitial"	involving a surgically-created cavity in a body
"brachytherapy"	radiation therapy delivered by a spatially-confined radioactive material inserted into the body at or near a tumor or other proliferative tissue disease site
"interstitial brachytherapy"	(no construction necessary)

"Inner spatial volume"

Cytyc's proposed construction	*Xoft's proposed construction*
A region of space surrounded by an outer spatial volume that is defined by an expandable surface element	Inner balloon in two-balloon device or spherical solid radionuclide in one-balloon device.

The phrase "inner spatial volume" appears in both patents-in-suit. The parties' arguments regarding the meaning of "inner spatial volume" are similar for each patent. The relevant portions of the specification are the same, and, additionally, the '204 patent purports to incorporate by reference the '813 patent. '204 patent, col. 1, ll. 10-11. The court will therefore construe "inner spatial volume" in the '204 patent in the same manner as for the '813 patent.

Claim Language	***Court's Construction***
"inner spatial volume"	a region of space surrounded by an outer spatial volume and either enclosed by a polymeric film wall or defined by the outside surface of a solid radionuclide sphere.

[11] The extrinsic evidence that Cytyc used "intercavitary" in literature and advertising in a manner that encompasses the definitions of "interstitial" and "intercavitary" it advances now, *see* Tr. at 93, is of little weight in this situation. Similarly, evidence presented by Cytyc that Xoft represented to the FDA that the term "interstitial" "is a more appropriate word for a cavity that is surgically created as compared to a natural body cavity," (*see* Decl. of Henry Su Supp. Cytyc's Scupplemental Claim Construction Br., Ex. A, is not entitled to significant weight although it does suggest that one skilled in the art construes the term as Cytyc proposes.

"Outer spatial volume"

Cytyc's proposed construction	*Xoft's proposed construction*
(no construction required) *or* A region of space defined by an expandable surface element and surrounding an inner spatial volume.	Balloon or cage.

The phrase "outer spatial volume" in the '204 patent is analogous to the "outer, closed, inflatable chamber" of the '813 patent. The "outer spatial volume" is also explained in a similar manner; it is "defined by an expandable surface element disposed proximate to the distal end of the body member in a surrounding relation to the inner spatial volume." '204 patent, col. 8, ll. 22-25. Xoft again confuses the concepts of a volume with the boundary of a volume. Cytyc's proposed construction is congruent with the language of claim 1 of the '204 patent, so the court will construe "outer spatial volume" as "a region of space defined by an expandable surface element and surrounding an inner spatial volume."

Claim Language	***Court's Construction***
"outer spatial volume"	a region of space defined by an expandable surface element and surrounding an inner spatial volume

"Expandable surface element"

Cytyc's proposed construction	*Xoft's proposed construction*
(no construction required) *or* A device that can be expanded or inflated, such as an expandable cage or an inflatable balloon.	Deflated balloon or collapsed cage.

Xoft's basic argument is that "expandable surface element" must be a deflated structure because once something is fully inflated, it is no longer expandable. Xoft also points out that part (d) of claim 1 refers to the "isodose profile" being "substantially similar in shape to the expandable surface element" without specifying whether the expandable surface element is fully expanded. It is apparent that the patentee intended "expandable surface element" to refer to a structure whether it was fully inflated or not. Xoft's proposed construction would have this element wink out of

existence at full inflation, leaving the "outer spatial volume" unbounded and giving the "isodose profile" no shape. The court agrees with Cytyc that no construction of the term is necessary.

Claim Language	*Court's Construction*
"expandable surface element"	(no construction needed)

"Radiation source"

Cytyc's proposed construction	*Xoft's proposed construction*
(no construction required)	radionuclide

The patent provides a clear definition of "brachytherapy": "The term 'brachytherapy,' as used herein, refers to radiation therapy delivered by a spatially confined radioactive material inserted into the body at or near a tumor or other proliferative tissue disease site." All asserted independent claims of the '204 patent contain the phrase "interstitial brachytherapy," which the court has construed as "radiation therapy delivered by a spatially-confined radioactive material inserted into the body at or near a tumor or other proliferative tissue disease site." Cytyc's argument that "radiation source" should not be constructed to exclude any radiation sources must be rejected; the claims clearly do not contemplate a radiation source other than "radioactive material."

There is still, however, the question of whether "radioactive material" means the same thing as Xoft's proposed construction of "radionuclide."[12] In describing the preferred embodiment, the patent says: "[t]he inner volume **30** is then filled with a material containing a predetermined radionuclide, for example, I-125, I-131, Yb-169 *or other source of radiation, such as radionuclides that emit photons, beta particles, gamma radiation, or other therapeutic rays.*" '204 patent, col. 4, ll. 9-13 (emphasis added). Since all the examples of sources of radiation given in the specification are radionuclides, the patentee appears to have intended to define "radioactive material" as "radionuclides." Cytyc argued at the *Markman* hearing that "or other therapeutic rays" could refer to other sources such as x-rays. The words "or other therapeutic rays," however, clearly refers to types

[12] The parties have agreed that "radionuclide" means "an isotope that undergoes radioactive decay."

of radionuclides. Cytyc's construction would require the patentee to have inserted the word "or" before "gamma radiation," indicating the end of the list of types of radionuclides.[13]

Dictionary definitions are consistent with construing "radiation source" as a "radionuclide." One definition of "radioactive" is "[a] descriptive term for a material made up of atoms in which radioactivity occurs." AMERICAN HERITAGE NEW DICTIONARY OF CULTURAL LITERACY (3d ed. 2006). A medical dictionary provided by Xoft defines "radioactive" as "giving off radiation as the result of the disintegration of the nucleus of an atom." MOSBY'S MEDICAL, NURSING, AND ALLIED HEALTH DICTIONARY, 1326 (Kenneth N. Anderson *et al.* eds., 4th ed. 1994). Cytyc has not presented evidence that one skilled in this art would understand "radioactive material" any differently. The court agrees with Xoft—the term "radioactive" in the context of the '204 patent does not encompass such radiation sources as x-ray tubes, and "radiation source" therefore should be taken to mean "radionuclide."

Claim Language	***Court's Construction***
"radiation source"	radionuclide

"Minimum prescribed dose"

Cytyc's proposed construction	*Xoft's proposed construction*
Minimum prescribed dose received within a target tissue for delivering therapeutic effects.	Minimum dose needed to treat cancer cells.

The parties have requested construction of the phrase "minimum prescribed dose" and point out that the term appears in claims 2, 18, 24, 32, and 36 of the '204 patent. The parties do not argue that the term should be construed differently for different claims. However, claims 2, 24, 32, and 36 contain the phrase "minimum prescribed absorbed dose," and claim 18 contains the phrase "prescribed absorbed dose." These inconsistencies seem irrelevant, however, because the parties'

[13] Cytyc also stated that this was an "Oxford comma" issue. Tr. at 137-38. However, in the sentence at issue, the Oxford comma is the one after "gamma radiation." Whether it is present does not alter the meaning of the sentence. Cytyc also argued that "we're in the land of eats, shoots and leaves." If Cytyc was referring to a book of such title, the court does not see how that would support Cytyc's argument; the theme of *Eats, Shoots & Leaves* is that punctuation should be used correctly. *See* Lynne Truss, *Eats, Shoots & Leaves: The Zero Tolerance Approach to Punctuation* (2004).

dispute is whether any such doses should be limited to treatment of cancer cells or allowed to cover any potential therapeutic effects. The court's construction of "brachytherapy" limits the claims to treatments "at or near a tumor or other proliferative tissue disease site." Xoft's proposed construction is too narrow, and Cytyc's is too broad. However, in light of the construction of "brachytherapy," no construction of "minimum prescribed dose" or similar phrases is necessary.

Claim Language	***Court's Construction***
"minimum prescribed dose"	(no construction necessary)

"Delivering a prescribed absorbed dose"

Cytyc's proposed construction	*Xoft's proposed construction*
(no construction required)	(indefinite)

Xoft argues that the patent does not reveal how one goes about prescribing a dose using the device, and that the phrase "delivering a prescribed absorbed dose" is therefore fatally indefinite. The '204 patent, however, describes a tool for treating proliferative tissue disease. A patent could adequately describe and claim a new apparatus or method for making the corrective curves in contact lenses, but a description of the particular curves a patient might require would not be necessary. If those skilled in the art would know how to use the disclosed invention, describing how to use it is unnecessary—the patentee merely needs to adequately describe the invention. Since Xoft bears the burden of proving that those skilled in the art would not know how to use the tool or method described in the patent and has presented no evidence on the subject, the court rejects Xoft's contention that the phrase is indefinite. No construction is necessary.

Claim Language	***Court's Construction***
"delivering a prescribed absorbed dose"	(no construction necessary)

"The inner and outer spatial volumes are configured to provide a minimum prescribed absorbed dose"

Cytyc's proposed construction	*Xoft's proposed construction*
The inner and outer spatial volumes are configured to provide a minimum prescribed absorbed dose for delivering	(indefinite)

"The inner and outer spatial volumes are configured to provide a minimum prescribed absorbed dose"

Cytyc's proposed construction	*Xoft's proposed construction*
Configuring the inner and outer spatial volumes to provide a minimum prescribed absorbed dose for delivering therapeutic effects to a target tissue.	(indefinite)

The phrases "the inner and outer spatial volumes are configured to provide a minimum prescribed absorbed dose" and "configuring the inner and outer spatial volumes to provide a minimum prescribed absorbed dose" are not indefinite for essentially the same reasons given in the previous section. As Cytyc again appears to be attempting to impermissibly broaden its claims to capture any therapeutic effect, despite the clear limitation provided by the patentee's definition of "brachytherapy," the court also cannot adopt Cytyc's proposed construction. No construction of the disputed language is necessary in light of the court's construction of other terms in the patent.

Claim Language	***Court's Construction***
"the inner and outer spatial volumes are configured to provide a minimum prescribed absorbed dose"	(no construction necessary)
"the inner and outer spatial volumes are configured to provide a minimum prescribed absorbed dose"	(no construction necessary)

"A minimum distance outward from the outer spatial volume expandable surface"

Cytyc's proposed construction	*Xoft's proposed construction*
(no construction required)	(indefinite)

Claims 2, 24, 32, and 36 all include the phrase "the target tissue being defined between the outer spatial volume expandable surface and a minimum distance outward from the outer spatial volume expandable surface."[14] Xoft asserts that "minimum distance" is indefinite in this context because the patent does not explain how the minimum distance is determined.

[14] The court believes that one skilled in the art would understand that the patentee intended to define "target tissue" as the tissue "between the outer spatial volume expandable surface and a minimum distance outward from the outer spatial volume expandable surface." Taken literally, the patent explains the physical location where the act of defining "target tissue" takes place.

Here, "minimum" does not appear to add anything to the patent. The "target tissue" is the tissue outside of the outer chamber for a fixed distance in all directions, but this fixed distance or how one determines it are not explained. It seems that one skilled in the art would know how to determine the distance. *See* Tr. at 85-89. But the patent may as well read "a short distance outward" or "a determined distance outward" or merely "a distance outward."

Cytyc claims that specification provides some guidance and that the minimum distance may in some instances be between half and one centimeter. The specification does state that

> device A can readily be configured to provide a dose in a therapeutic range, say between 40 to 60 Gray, at a distance between 0.5 and 1.0 cm from the outer spatial volume for an outer spatial volume having a diameter of 4.0 cm and being in contact with the resection cavity wall.

'204 patent, col. 6, ll. 31-35. However, Cytyc neglects to mention that "device A" is "an interstitial brachytherapy apparatus . . . such as those employed in U.S. Pat. No. 5,429,582, having a single spatial volume **50** filled with a radioactive material in solution." '204 patent, col. 6, ll. 3-7. In any case, this discussion does not use the phrases "target tissue" or "a minimum distance outward." Nevertheless, Xoft has presented no evidence that one skilled in the art would not understand the phrase "the target tissue being defined between the outer spatial volume expandable surface and a minimum distance outward from the outer spatial volume expandable surface." Xoft has not met its burden of proving by clear and convincing evidence that this language is indefinite, and the court finds that no construction is necessary.

Claim Language	***Court's Construction***
"a minimum distance outward from the outer spatial volume expandable surface"	(no construction necessary)

"Controlled dose"

Cytyc's proposed construction	*Xoft's proposed construction*
(no construction required)	(indefinite)

"To reduce or prevent necrosis in healthy tissue proximate to the expandable surface"

Cytyc's proposed construction	*Xoft's proposed construction*
(no construction required)	(indefinite)

"Providing a controlled dose at the outer spatial volume expandable surface to reduce or prevent necrosis in healthy tissue"

Cytyc's proposed construction	*Xoft's proposed construction*
Controlling the ratio of the dose at the expandable surface of the outer spatial volume to the prescribed dose at the depth of interest in the target issue so that the dose at the expandable surface is not so high that it lethally damages cells in healthy tissue in contact with the expandable surface	(indefinite)

Xoft argues that the patent does not reveal how one goes about controlling a dose using the device and that "reducing necrosis" is a hopelessly vague concept, making the '204 patent indefinite. Xoft, however, has presented no evidence that one skilled in the art would not be able to understand the patent and has again failed to meet its burden of proof. The court will therefore adopt Cytyc's construction proposals. "Providing a controlled dose at the outer spatial volume expandable surface to reduce or prevent necrosis in healthy tissue" means "controlling the ratio of the dose at the expandable surface of the outer spatial volume to the prescribed dose at the depth of interest in the target issue so that the dose at the expandable surface is not so high that it lethally damages cells in healthy tissue in contact with the expandable surface."

Claim Language	***Court's Construction***
"controlled dose"	(no separate construction necessary)
"to reduce or prevent necrosis in healthy tissue proximate to the expandable surface"	(no separate construction necessary)
"providing a controlled dose at the outer spatial volume expandable surface to reduce or prevent necrosis in healthy tissue"	controlling the ratio of the dose at the expandable surface of the outer spatial volume to the prescribed dose at the depth of interest in the target issue so that the dose at the expandable surface is not so high that it lethally damages cells in healthy tissue in contact with the expandable surface

"Adapting the expandable surface to contact tissue surrounding the resection cavity to conform the tissue"

Cytyc's proposed construction	*Xoft's proposed construction*
(no construction required)	(indefinite)

Xoft's contention that this phrase is indefinite springs from its argument that "expandable surface element" means "deflated balloon or cage." As the court has rejected Xoft's interpretation of "expandable surface element," no construction of "adapting the expandable surface to contact tissue surrounding the resection cavity to conform the tissue" is necessary.

Claim Language	***Court's Construction***
"adapting the expandable surface to contact tissue surrounding the resection cavity to conform the tissue"	(no construction necessary)

"Desired shape of the expandable surface element"

Cytyc's proposed construction	*Xoft's proposed construction*
(no construction required)	(indefinite)

Xoft has again presented no evidence to back up an argument that the phrase is indefinite and therefore again fails to carry its burden of proof. No construction of "desired shape of the expandable surface element" is necessary.

Claim Language	***Court's Construction***
"desired shape of the expandable surface element"	(no construction necessary)

"Predetermined spacing"

Cytyc's proposed construction	*Xoft's proposed construction*
(no construction required)	(indefinite)

"A predetermined spacing is provided between said inner spatial volume and the expandable surface element" / "A predetermined spacing between said inner spatial volume and the expandable surface element"

Cytyc's proposed construction	*Xoft's proposed construction*
The distance between the inner spatial volume and the expandable surface element is determined in advance	(indefinite)

Xoft's contention that these phrases are indefinite is based on its argument that "expandable surface element" means "deflated balloon or cage," and Xoft has again presented no evidence to back up arguments that the phrases are indefinite. No construction of "predetermined spacing" is necessary. The court will adopt Cytyc's proposals and define both of the long phrases ("a predetermined spacing is provided between said inner spatial volume and the expandable surface element" and "a predetermined spacing between said inner spatial volume and the expandable surface element") as "the distance between the inner spatial volume and the expandable surface element is determined in advance."

Claim Language	***Court's Construction***
"predetermined spacing"	(no construction necessary)
"a predetermined spacing is provided between said inner spatial volume and the expandable surface element" / "a predetermined spacing between said inner spatial volume and the expandable surface element"	the distance between the inner spatial volume and the expandable surface element is determined in advance

"Intraoperatively"

Cytyc's proposed construction	*Xoft's proposed construction*
(no construction required) *or* During the surgical operation to remove proliferative tissue.	After surgical removal of tumor but prior to closing the surgical site

At the claim construction hearing, the parties appeared to agree on the definition of "interoperatively." *See* Tr. at 140. The previous apparent disagreement revolved around whether the surgical site could be closed before insertion of the catheter apparatus. The court understands that the parties agree that the catheter must be inserted before the surgical site is closed. The '204 patent at column 7, lines 55-64, specifically refers to the catheter being inserted "[f]ollowing tumor resection, but prior to closing the surgical site."

Claim Language	***Court's Construction***
"intraoperatively"	following tumor resection, but prior to closing the surgical site

"Solid radiation source"

Cytyc's proposed construction	*Xoft's proposed construction*
A radiation source that has a fixed shape and volume, and is not deformable	Solid radionuclide

The parties' primary dispute here is whether "radiation source" encompasses more than radionuclides, which the court addressed above to limit "radiation source" to radionuclides. Cytyc presents a dictionary definition of "solid," namely, "of definite shape and volume; not liquid or gaseous," from the AMERICAN HERITAGE COLLEGE DICTIONARY, 1295 (3d ed. 1997). The court will therefore define "solid radiation source" as "a radionuclide of definite shape and volume; not liquid or gaseous."

Claim Language	***Court's Construction***
"solid radiation source"	a radionuclide of definite shape and volume; not liquid or gaseous

"The prescribed absorbed dose is delivered to the target tissue in substantially three dimensions"

Cytyc's proposed construction	*Xoft's proposed construction*
The prescribed absorbed dose is delivered to the target tissue such that all points at a given outward distance from the tissue wall will receive the same dose.	(indefinite)

Xoft contends that "prescribed absorbed dose" and "in substantially three dimensions" render "the prescribed absorbed dose is delivered to the target tissue in substantially three dimensions" fatally indefinite. The court has already rejected Xoft's argument regarding "prescribed absorbed dose."

Xoft points to Cytyc's expert's testimony that "there's no such thing as substantially three dimensions" because something is either three dimensional or not. Mulville Decl. (dkt. # 51), Ex. L (Verhey Decl.) at 153. Cytyc points to Xoft's expert's testimony that he could envision a brachytherapy apparatus that delivered 99 percent of its radiation in a plane; Cytyc claims such a flat radiation field would not be in substantially three dimensions. Though a closer question than some of Xoft's other indefiniteness contentions, the court nonetheless finds that Xoft has not shown by clear and convincing evidence that one skilled in the art would not understand "in substantially three

dimensions" in the manner put forth by Cytyc. The court therefore adopts Cytyc's proposed construction for "the prescribed absorbed dose is delivered to the target tissue in substantially three dimensions," namely, "the prescribed absorbed dose is delivered to the target tissue such that all points at a given outward distance from the tissue wall will receive the same dose."

Claim Language	***Court's Construction***
"the prescribed absorbed dose is delivered to the target tissue in substantially three dimensions"	the prescribed absorbed dose is delivered to the target tissue such that all points at a given outward distance from the tissue wall will receive the same dose

III. ORDER

1. For the reasons given above, the court adopts the following claim construction as detailed in this order.

Term or phrase	Court's construction
"inner spatial volume"	a region of space surrounded by an outer spatial volume and either enclosed by a polymeric film wall or defined by the outside surface of a solid radionuclide sphere.
"outer, closed, inflatable chamber"	outer, closed, inflatable chamber
"predetermined constant spacing"	(no construction necessary)
"predetermined constant spacing between said inner spatial volume and radiation transparent wall"	spacing predetermined by one skilled in the art between the wall or edge of the inner spatial volume and the radiation transparent wall of the outer, closed, inflatable chamber, when inflated, which is constant in all directions if the outer chamber is spherical, or constant along a radial plane if the outer chamber is not spherical
"rendering uniform"	to make the absorbed dose of radiation more uniform to prevent over-treatment of body tissue at or close to the outer wall of the instrument
"Means . . . for rendering uniform the radial absorbed dose profile of the emissions"	Function: Making the absorbed dose of radiation more uniform to prevent over-treatment of body tissue at or close to the outer wall of the instrument. Structure: A radiation absorbing or attenuating material, *e.g.*, air, x-ray contrast fluid, contrast media used in angiography, water, a gas, or barium sulfate or their equivalents.
"The radioactive material"	The material of claim 1 containing a radionuclide.
"A plurality of radioactive solid particles placed at predetermined locations within the inner spatial volume to provide a desired composite radiation profile"	(no construction needed)
"interstitial"	involving a surgically-created cavity in a body
"brachytherapy"	radiation therapy delivered by a spatially-confined radioactive material inserted into the body at or near a tumor or other proliferative tissue disease site
"interstitial brachytherapy"	(no construction necessary)

"outer spatial volume"	a region of space defined by an expandable surface element and surrounding an inner "expandable surface element"(no construction needed)
"radiation source"	radionuclide
"minimum prescribed dose"	(no construction necessary)
"delivering a prescribed absorbed dose"	(no construction necessary)
"the inner and outer spatial volumes are configured to provide a minimum prescribed absorbed dose"	(no construction necessary)
"the inner and outer spatial volumes are configured to provide a minimum prescribed absorbed dose"	(no construction necessary)
"a minimum distance outward from the outer spatial volume expandable surface"	(no construction necessary)
"controlled dose"	(no separate construction necessary)
"to reduce or prevent necrosis in healthy tissue proximate to the expandable surface"	(no separate construction necessary)
"providing a controlled dose at the outer spatial volume expandable surface to reduce or prevent necrosis in healthy tissue"	controlling the ratio of the dose at the expandable surface of the outer spatial volume to the prescribed dose at the depth of interest in the target issue so that the dose at the expandable surface is not so high that it lethally damages cells in healthy tissue in contact with the expandable surface
"adapting the expandable surface to contact tissue surrounding the resection cavity to conform the tissue"	(no construction necessary)
"desired shape of the expandable surface element"	(no construction necessary)
"predetermined spacing"	(no construction necessary)
"a predetermined spacing is provided between said inner spatial volume and the expandable surface element" / "a predetermined spacing between said inner spatial volume and the expandable surface element"	the distance between the inner spatial volume and the expandable surface element is determined in advance
"intraoperatively"	following tumor resection, but prior to closing the surgical site
"solid radiation source"	a radionuclide of definite shape and volume; not liquid or gaseous

"the prescribed absorbed dose is delivered to the target tissue in substantially three dimensions"	the prescribed absorbed dose is delivered to the target tissue such that all points at a given outward distance from the tissue wall will receive the same dose

2. The parties shall appear for a further case management conference on June 1, 2007 at 10:30 a.m. and shall file a further joint case management conference statement no later than four days prior.

DATED: 4/27/07

Ronald M. Whyte

RONALD M. WHYTE
United States District Judge

Notice of this document has been electronically sent to:

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Counsel are responsible for distributing copies of this document to co-counsel that have not registered for e-filing under the court's CM/ECF program.

Dated: 4/27/07

SPT
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Attorneys for Defendant and Counterclaimant
CYTYC CORPORATION

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

XOFT, INC., Plaintiff, vs. CYTYC CORPORATION AND PROXIMA THERAPEUTICS, INC., Defendants. AND RELATED COUNTERCLAIMS.	**Case No. C-05-05312-RMW** **DEFENDANT CYTYC CORPORATION'S ADMINISTRATIVE MOTION UNDER CIVIL LOCAL RULE 3-12(B) TO CONSIDER WHETHER CASES SHOULD BE RELATED**

Defendant Cytyc Corporation ("Cytyc") hereby respectfully submits this Administrative Motion to Consider Whether Cases Should Be Related, pursuant to Civil Local Rules 3-12 and 7-11 of this Court.

ACTION REQUESTED

Now pending in this Court is a patent infringement action by Cytyc and co-plaintiffs Hologic, Inc. and Hologic L.P., against defendant SenoRx, Inc. (the *Hologic* action), identified by the following title and case number:

> *Hologic, Inc., et al. v. SenoRx, Inc.*, Case No. C-08-00133-MEJ
> (filed January 8, 2008, and assigned to the Honorable Maria-Elena James)[1]

Cytyc respectfully requests that this Court enter an Order under Civil Local 3-12(f) finding that this action, identified by the following title and case number:

> *Xoft, Inc. v. Cytyc Corporation, et al.*, Case No. C-05-05312-RMW
> (which was pending in this Court until its termination by a stipulation and order of dismissal on August 14, 2007)

and the *Hologic* action are related.

REASONS SUPPORTING THE MOTION

Civil Local Rule 3-12(b) directs a party to file an administrative motion to consider whether "an action, filed in or removed to this district is (or the party believes that the action may be) related to an action which is *or was pending in this District* as defined in Civil L.R. 3-12(a)." N.D. CAL. CIV. L.R. 3-12(b) (emphasis added). Cytyc submits that the two actions are related for the following reasons within the meaning of Civil Local Rule 3-12(a):

- Each action involved or involves Cytyc Corporation as a party;
- Each action included or includes claims seeking infringement, validity and/or enforceability of the following U.S. Patents that were formerly assigned to Cytyc and are now assigned to Hologic, Inc., namely, U.S. Patent Nos. 5,913,813 and 6,413,204;

[1] A copy of the filed Complaint and exhibits is attached as Exhibit A to the Declaration of Henry C. Su.

- In the context of this action, this Court has already construed several terms of the aforementioned patents-in-suit.

Accordingly, both actions concern "substantially the same parties, property, transaction or event," and "it appears likely that there will be an unduly burdensome duplication of labor and expense or conflicting results if the cases are conducted before different Judges." N.D. CAL. CIV. L.R. 3-12(a).

For the foregoing reasons, Cytyc respectfully requests that this Court determine that the *Hologic* action and this action are related under Civil Local Rule 3-12(a) and enter an order to that effect. A Declaration and proposed Order accompany this Administrative Motion.

Dated: January 9, 2008

HOWREY LLP

By: /s/ Henry C. Su
Henry C. Su

Attorneys for Defendant Cytyc Corporation

CERTIFICATE OF SERVICE

I do hereby certify that on January 9, 2008 a true and correct copy of

1. DEFENDANT CYTYC CORPORATION'S ADMINISTRATIVE MOTION UNDER CIVIL LOCAL RULE 3-12(B) TO CONSIDER WHETHER CASES SHOULD BE RELATED

2. DECLARATION OF HENRY C. SU IN SUPPORT OF DEFENDANT CYTYC CORPORATION'S ADMINISTRATIVE MOTION UNDER CIVIL LOCAL RULE 3-12(B) TO CONSIDER WHETHER CASES SHOULD BE RELATED

3. PROPOSED ORDER GRANTING DEFENDANT CYTYC CORPORATION'S ADMINISTRATIVE MOTION UNDER CIVIL LOCAL RULE 3-12(B) TO CONSIDER WHETHER CASES SHOULD BE RELATED

were served on the interested parties in said action, as follows:

By **PERSONAL SERVICE** to: SenoRx, Inc.
c/o CT Corporation System
818 W. Seventh Street
Los Angeles, CA 90017
(The documents will have been served along with the Summons and Complaint)

By **ELECTRONIC TRANSMISSION** via the Court's ECF System to Counsel for Xoft, Inc. at Orrick, Herrington & Sutcliffe.

Executed on January 9, 2008 at East Palo Alto, California.

/s/ Henry C. Su
Henry C. Su
Counsel for Cytyc Corporation

Press Release

SENORX ANNOUNCES 510(k) CLEARANCE FOR ITS MULTI-LUMEN RADIATION BALLOON

ALISO VIEJO, California, May 23, 2007 – SenoRx (NASDAQ: SENO) today announced that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market its Multi-Lumen Radiation Balloon Applicator for brachytherapy. The Multi-Lumen Radiation Balloon is intended to provide brachytherapy to the surgical margins following lumpectomy for breast cancer. The company believes that its Multi-Lumen Radiation Balloon can play an important role in the paradigm shift from traditional whole breast radiation therapy to localized partial breast radiation therapy. The radiation balloon uses vacuum to remove excess fluid and to adhere closely to often irregularly shaped lumpectomy cavities in order to deliver precise radiation dosing through multiple seed lumens.

“We are excited at the prospect that our radiation balloon product may actually expand the balloon market,” said Lloyd Malchow, SenoRx President and Chief Executive Officer. “Certain patients who are presently candidates for balloon therapy are currently excluded because of the location of the lesion relative to their breast size. Our multi-lumen approach offers a solution to this problem.”

The company expects to ship product for post-FDA clearance human clinical trials supporting marketing claims and host clinical education events in the second half of 2007. Full launch of the Radiation Balloon product is expected in early 2008.

About SenoRx

SenoRx (NASDAQ: SENO), which completed its initial public offering of common stock in March 2007, develops, manufactures and sells minimally invasive medical devices used by breast care specialists for the diagnosis of breast cancer. SenoRx’s field sales organization serves over 1,000 breast diagnostic and treatment centers in the United States and Canada. With 16 products that have already received FDA 510(k) clearance across the continuum of breast care, SenoRx is developing additional minimally invasive products for diagnosis and treatment of breast cancer. For more information, visit the company’s website at www.senorx.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Specifically, statements concerning SenoRx's ability to successfully expand the balloon market, offering a solution for patients that are not otherwise candidates for balloon therapy, as well as statements about the timing of full commercial launch of the Multi-Lumen Radiation Balloon, are forward-looking statements within the meaning of the Safe Harbor. Forward-looking statements are based on management's current, preliminary expectations and are subject to risks and uncertainties, which may cause SenoRx's actual results to differ materially from the statements contained herein. Further information on potential risk factors that could affect SenoRx's business and its financial results are detailed in its quarterly report on Form 10-Q as filed with the Securities and Exchange Commission on May 15, 2007. Undue reliance should not be placed on forward-looking statements, which speak only as of the date they are made. SenoRx undertakes no obligation to update publicly any forward-looking statements to reflect new information, events or circumstances after the date they were made, or to reflect the occurrence of unanticipated events.

CONTACT: SenoRx, Inc.
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949-362-4800 x132

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

HOLOGIC, INC., CYTYC CORPORATION, and HOLOGIC LP, Plaintiffs, vs. SENORX, INC., Defendant.	Case No. C08-00133-MEJ **NOTICE OF MANUAL FILING** **Date: March 20, 2008** **Time: 10:00a.m.** **Courtroom: B, 15th floor** **Judge: Hon. Maria-Elena James**

Regarding: **__DECLARATION OF GLENN MAGNUSON IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION**

This filing is in paper or physical form only, and is being maintained in the case file in the Clerk's office. If you are a participant in this case, this filing will be served in hard-copy shortly. For information on retrieving this filing directly from the court, please see the court's main web site at http://www.cand.uscourts.gov under Frequently Asked Questions (FAQ).

This filing was not efiled for the following reason(s):

[X] Item Under Seal

Dated: February 6, 2008

HOWREY LLP

By: /s/
Katharine L. Altemus

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

HOLOGIC, INC., CYTYC CORPORATION, and HOLOGIC LP, Plaintiffs, vs. SENORX, INC., Defendant.	Case No. C08-00133-MEJ **CIVIL LOCAL RULE 79-5(B) AND (C) ADMINISTRATIVE MOTION TO FILE UNDER SEAL CONFIDENTIAL PORTIONS OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION AND THE ENTIRE CONFIDENTIAL SUPPORTING DECLARATION OF GLENN MAGNUSON** **Date: March 20, 2008** **Time: 10:00a.m.** **Courtroom: B, 15th floor** **Judge: Hon. Maria-Elena James**

PLEASE TAKE NOTICE that pursuant to Civil Local Rule 79-5(b) and (c), Plaintiffs Hologic, Inc., Cytyc Corporation, And Hologic LP (Collectively, "Plaintiffs" or "Hologic") hereby move the Court for an administrative order to file under seal select portions of Plaintiffs' Motion For Preliminary Injunction and the entire Declaration of the Glenn Magnuson in Support of Plaintiffs' Motion For Preliminary Injunction.

Both the Motion For Preliminary Injunction and the supporting Declaration of Glenn Magnuson contain confidential Hologic business information.

Dated: February 6, 2008

By: /s/
Katharine L. Altemus

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

HOLOGIC, INC., CYTYC CORPORATION, and HOLOGIC LP, Plaintiffs, vs. SENORX, INC., Defendant.	Case No. C08-00133-MEJ **DECLARATION OF KATHARINE L. ALTEMUS IN SUPPORT OF PLAINTIFFS' CIVIL LOCAL RULE 79-5(B) AND (C) ADMINISTRATIVE MOTION TO FILE UNDER SEAL CONFIDENTIAL PORTIONS OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION AND THE ENTIRE CONFIDENTIAL SUPPORTING DECLARATION OF GLENN MAGNUSON** **Date: March 20, 2008** **Time: 10:00a.m.** **Courtroom: B, 15th floor** **Judge: Hon. Maria-Elena James**

I, Katharine L. Altemus, declare as follows:

1. I am an associate in the law firm Howrey LLP and a member of the Bar of this court, and I serve as one of the outside counsel for Hologic, Inc., Cytyc Corporation and Hologic LP

(collectively "Plaintiffs" or "Hologic"). The following declaration is based on my personal knowledge, and if called upon to testify, I could and would competently testify as to the matters set forth herein.

2, In support of Plaintiffs' Administrative Motion To File Under Seal Confidential Portions Of Plaintiffs' Motion For Preliminary Injunction And The Entire Confidential Supporting Declaration Of Glenn Magnuson, Hologic respectfully requests that the Confidential Version of Plaintiffs' Motion For Preliminary Injunction And The Entire Confidential Supporting Declaration Of Glenn Magnuson be maintained under seal.

3. Plaintiffs' Motion For Preliminary Injunction contains throughout its pages information that is internal, confidential and sensitive to Hologic and its employees, and the unprotected distribution of this transcript in its unredacted form to the general public could cause harm to Hologic and its employees.

4. The Declaration of Glenn Magnuson In Support Of Plaintiffs' Motion for Preliminary Injunction contains throughout its pages information that is internal, confidential and sensitive to Hologic and its employees, and the unprotected distribution of this transcript in its unredacted form to the general public could cause harm to Hologic and its employees.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: February 6, 2008

HOWREY LLP

By: /s/
Katharine L. Altemus

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

HOLOGIC, INC., CYTYC CORPORATION, and HOLOGIC LP, Plaintiffs, vs. SENORX, INC., Defendant.	Case No. C08-00133-MEJ **[PROPOSED] ORDER GRANTING PLAINTIFFS' ADMINISTRATIVE MOTION TO FILE UNDER SEAL CONFIDENTIAL PORTIONS OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION AND THE ENTIRE CONFIDENTIAL SUPPORTING DECLARATION OF GLENN MAGNUSON** **Date: March 20, 2008** **Time: 10:00a.m.** **Courtroom: B, 15th floor** **Judge: Hon. Maria-Elena James**

[PROPOSED] ORDER

The Court, having considered Plaintiffs' Administrative Motion To File Under Seal Confidential Portions Of Plaintiffs' Motion For Preliminary Injunction And The Entire Confidential Supporting Declaration Of Glenn Magnuson, finds that good cause exists pursuant to Civil L.R. 79-5 for the Motion and hereby orders that the Motion is GRANTED in its entirety.

The clerk shall maintain under Seal the Confidential Versions Of Plaintiffs' Motion For Preliminary Injunction and the Declaration of Glenn Magnuson In Support Of Plaintiffs' Motion For Preliminary Injunction.

It is SO ORDERED.

Dated: _____, 2008

_____
Maria-Elena James
United States District Court Judge

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

HOLOGIC, INC., CYTYC CORPORATION, and HOLOGIC LP, Plaintiffs, vs. SENORX, INC., Defendant.	Case No. C08-00133-MEJ **PROOF OF SERVICE** **Date: March 20, 2008** **Time: 10:00a.m.** **Courtroom: B, 15th floor** **Judge: Hon. Maria-Elena James**

I am employed in the County of San Francisco, State of California. I am over the age of 18 and not a party to the within action. My business address is 525 Market Street, Suite 3600, San Francisco, California 94105.

On February 6, 2008, I served on the interested parties in said action a true copy of:

PLAINTIFFS' NOTICE OF MOTION AND MOTION FOR PRELIMINARY INJUNCTION

DECLARATION OF KATHERINE L. ALTEMUS IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

NOTICE OF MANUAL FILING OF DECLARATION OF GLENN MAGNUSON IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

CIVIL LOCAL RULE 79-5(B) AND (C) ADMINISTRATIVE MOTION TO FILE UNDER SEAL CONFIDENTIAL PORTIONS OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION AND THE ENTIRE CONFIDENTIAL SUPPORTING DECLARATION OF GLENN MAGNUSON

DECLARATION OF KATHARINE L. ALTEMUS IN SUPPORT OF PLAINTIFFS' CIVIL LOCAL RULE 79-5(B) AND (C) ADMINISTRATIVE MOTION TO FILE UNDER SEAL CONFIDENTIAL PORTIONS OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION AND THE ENTIRE CONFIDENTIAL SUPPORTING DECLARATION OF GLENN MAGNUSON

[PROPOSED] ORDER GRANTING PLAINTIFFS' ADMINISTRATIVE MOTION TO FILE UNDER SEAL CONFIDENTIAL PORTIONS OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION AND THE ENTIRE CONFIDENTIAL SUPPORTING DECLARATION OF GLENN MAGNUSON

☒ (MAIL) I am readily familiar with this firm's practice of collection and processing correspondence for mailing. Under that practice it would be deposited with the U.S. postal service on that same day in the ordinary course of business. I am aware that on motion of party served, service is presumed invalid if postal cancellation date or postage meter date is more than 1 day after date of deposit for mailing in affidavit.

☒ (eMAIL) I am readily familiar with this firm's practice of serving documents via electronic mail. Under that practice, today I will send via my business email address a copy of each document listed herein as an attachment to the email address(es) listed below.

F.T. Alexandra Mahaney
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I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed on February 6, 2008, at San Francisco, California.

/s/
Grady Johnson